REPORT TO THE NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

HAZARD ASSESSMENT AND REVIEW OF CURRENT CONTROLS ON THE USE OF LEAD IN SURFACE COATINGS, INKS, COSMETICS AND TOILETRIES

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(**NB:** due to alterations in this document and the need for many more additions, the page numbers in the contents will need to be updated as the document is finalised. xxx)

1. INTRODUCTION

1.1 Acronyms

(NB: Not all of these have been used in the current report. Some of them are for future reference only) [xxx – ensure all acronyms used in the report are included and any not used are not listed here]

ACCC: Australian Competition and Consumer Commission
ACCORD: Advocate for the Consumer, Cosmetic, Hygiene & Specialty Products Industry (Australia)
ADG code: Australian Dangerous Goods code
AICS: Australian Inventory of Chemical Substances
APMF: Australian Paint Manufacturers Federation
APAS: Australian Paint Approval Scheme
AS: Australian Standard
ASCC: Australian Safety and Compensation Council
ATSDR: Agency for Toxic Substances and Disease Registry (USA)
BCCA: Blast Cleaning and Coating Association (NSW)
BCF: British Coating Federation
CAS No.: Chemical Abstracts Service number
CDC: Centers for Disease Control and Prevention (USA)
CEC: Council of the European Communities
CHIP: Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (UK)
CIR: Cosmetic Ingredient Review (USA)
CPSC: Consumer Product Safety Commission (USA)
CTFA: Cosmetic, Toiletry & Fragrance Association (USA)
CTFAA: Cosmetic, Toiletry and Fragrance Association of Australia
EEC: European Economic Community
EINECS: European Inventory of Existing Commercial chemical Substances

EPA: Environmental Protection Agency (USA)

FDA: Food and Drug Administration (USA)

GMP: Good Manufacturing Practice

HSIS: Hazardous Substances Information System

ILO: International Labor Organization

INCI: International Nomenclature Cosmetic Ingredient

IPPIC: International Paint and Printing Ink Council

MPA: Master Painters Australia

NDPSC: National Drugs and Poisons Schedule Committee (Australia)

NOHSC: National Occupational Health and Safety Commission (Australia)

NICNAS: National Industrial Chemicals Notification and Assessment Scheme (Australia)

OLDP: Office of Legislative Drafting and Publishing (Australia)

PACIA: Plastics and Chemicals Industry Association (Australia)

SA: Standards Australia

SCAA: Surface Coatings Association of Australia

SCANZ: Surface Coatings Association of New Zealand

SCCNFP: Scientific Committee on Cosmetics and Non-Food Products (European Communities)

SHARP: Safety & Health Assessment & Research for Prevention (USA)

SRC: Safety, Rehabilitation and Compensation Commission (Australia)

SUSDP: Standard for the Uniform Scheduling of Drugs and Poisons (Australia)

NIOSH: National Institute for Occupational Health and Safety (USA)

NPCA: National Paint and Coatings Association (USA)

NPI: National Pollutant Inventory (Australia)

OECD: Organization for Economic Co-operation and Development

OSHA: Occupational Safety and Health Administration (USA)

OHS(CE) Act: Occupational Health and Safety Commonwealth Employment Act (1991) (Australia)

SSPC: Society for Protective Coatings (USA)

TSCA: Toxic Substances Control Act (USA)

1.2 About NICNAS

The Industrial Chemicals (Notification and Assessment) Act in 1989 (Cat. No. 90 4035 0) was developed so as to establish a national system of notification and assessment for industrial chemicals. Such a procedure ensures that hazardous chemicals are handled in a safe and appropriate manner during their manufacture and use so that any adverse effects are avoided (NICNAS, 2005a). As the provider of the national notification and assessment scheme, NICNAS is an essential part of the 1989 Act, ensuring the protection of workers, the public and the environment to the harmful effects of industrial chemicals. In general NICNAS has two main roles; it both assesses any new chemicals introduced to Australia, and conducts assessments on chemicals already in use (existing chemicals) on a priority basis. These existing chemical assessments are performed in response to concerns surrounding the hazards to health and/or to the environment of the substances. As a departmental body, NICNAS is located in the Office of Chemical Safety, within the Therapeutic Goods Administration (TGA) regulatory groups. These are all part of the Australian Government Department of Health and Ageing (NICNAS, 2005a).

1.3 NICNAS's Approach to Risk Assessments:

The approach taken by NICNAS is dependent upon the type of chemical under assessment. In the case of Priority Existing Chemicals (PEC), a quantitative risk assessment is able to measure the risk posed by the chemical. As Lead and its various compounds are already in use in Australia, it is this methodology that will be utilized.

There are two different types of assessments conducted by NICNAS. The first of these is the full assessment which is a process undertaken to determine any adverse health and/or environmental effects arising from the import, export, manufacture, use, storage and disposal of the chemical and to conduct an assessment of the risks to workers, the public and the environment from use of the chemical in Australia (NICNAS, 2005a). The preliminary assessment, on the other hand, focuses on one or more of the elements covered in a full assessment but does not include any assessment of risk (NICNAS,

2005a). The results of this preliminary assessment are used to identify any prevalent concerns relating to the chemical, and it is then decided whether a full assessment should be conducted.

1.4 About Priority Existing Chemicals (PEC)

A PEC is an industrial chemical that has been selected for assessment because there are reasons to believe that the "manufacture, handling, storage, use or disposal of the chemical gives rise, or may give rise, to a risk of adverse health and/or environmental effects" (NICNAS, 2005a). A chemical is declared as a PEC for assessment by the Minister for Health and Ageing following a recommendation from the director of NICNAS. Once a chemical is considered to be a PEC, anyone wishing to import or manufacture it must lodge an application for assessment with NICNAS. They may also be asked to provide information about the chemical, which will assist in the completion of the risk assessment. A PEC cannot be imported into or manufactured in Australia unless the introducer has applied to NICNAS for assessment of the PEC (NICNAS, 2005a).

1.5 The Case for Lead

While lead salts in cosmetics have not officially been declared PECs, the intention of this report is to provide the department with information regarding the regulatory and voluntary industry controls for both the public and industrial users so NICNAS can evaluate the need to declare the lead salts used for these purposes as PECs for full assessment. Lead salts used in surface coatings and inks however have been declared as PECs for health risk assessment. NICNAS has currently been working with the Australian Paint Manufacturers Federation (APMF) and the surface coating industry to collect information on lead salts used in surface coatings and inks.

1.5.1 Brief History of the Use of Lead in Surface Coatings and Inks

Lead has been used as a key ingredient in paints and primers over the last 100 years due to its excellent ability to protect surfaces from corrosion (Standards Australia, 1995). In Australia the use of Lead compounds in domestic surface coatings and paints on the market today has been largely eliminated. In 1998, The LEAD Group commissioned a factsheet on the historical use of lead in paints from John Hartley (d. 2001) of The Blast Cleaning and Coating Association (BCCA) of Australia and he kindly wrote the factsheet entitled: "USE OF LEAD IN PAINT IN NSW - WHEN AND WHERE IT WAS USED." John Hartley began his career as a paint chemist in Australia in 1955. He worked in Victoria, Tasmania and New South Wales, and was a walking encyclopaedia on all protective coatings matters but had a special interest in history. John was awarded the 1999 Australasian Corrosion Association (ACA) Victor Nightingall award for his outstanding contribution to the protective coatings industry in Australia and New Zealand (Francis, 2000). In January 2006, Mary Reid, Secretary of BCCA NSW kindly gave permission for the factsheet to be reproduced within this report to NICNAS (see next page).

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USE OF LEAD IN PAINT IN NSW - WHEN AND WHERE IT WAS USED

The recent past there has been a move away from the use of white lead and of lead compounds generally in paint for the retail market. Although the use of lead pigments has continued for industrial paints used on motor vehicles railway rolling stock and industrial buildings and bridges and similar public utilities, the use of white lead as the prime white pigment for a durable paint coating ceased in approximately 1958. Although the use of coloured lead pigment continued for some years after this the closing of some pigment factories making coloured lead pigments in 1972 means that as far as domestic construction is concerned those buildings erected since 1972 may be expected to be free of paint which contains lead in a pigment form.

Between 1958 and 1972 there was gradual reduction in the quantity of lead pigment used for tinting or colouring of paints both exterior and interior.

Indeed the most valuable characteristic of the lead chromate pigments was their durability when exposed to the weather so that the use of these -colours continued well into the 1960s in the product ranges of some paint manufacturers.

To this day lead pigments are made in NSW and used on industrial buildings.

Around about this time however a white pigment known as calcium orthoplumbate was imported in considerable quantities and promoted for incorporation into primers for

galvanised iron, galvanised steel and those steel surfaces which were thermally sprayed with metallic zinc. (An instance of this was the second road bridge over the Hawkesbury River, the box girders of which were abrasive blasted, metallised with zinc spray and then this was primed with calcium plumbate primer. Upon this was applied green exterior paint, which was pigmented with lead chromate.)

THE PERIOD FROM 1940 TO 1960

Bear in mind that the sale of paint was controlled by the government during the war years and that a shortage of manufacture in the post war years up until 1950 led to a rationing of the sales of white lead base paints. The post war use of white lead paints for interior work was much less than had been the practice before the war. So it became common to use on domestic construction white lead paints upon the exterior including verandah joinery etc whereas the period from 1950 onwards was particularly marked with the development of water based paints for indoor use. The water-based paints which were then used included what were well known brands Muraltone and Kemtone which were alkyd resin emulsion paints. In this class of paint the white pigment lithopone a zinc sulphide based pigment, displaced white lead as the white pigment. These became extensively used for the painting of walls and ceilings to a large extent displacing the use of calcimines and distempers, which had characterised the years from 1940 to 1950.

Of course in public buildings the use of lead, that is, white lead containing paints as primers and undercoats on interior walls and timber trim continued unabated during this period.

BEFORE 1939

Early colonial times did not use a great deal of red lead or of white lead on domestic construction. But in buildings of that age there would be considerable amounts of toxic mercurial pigments such as vermilion and arsenic greens such as emerald green. These

were imported as pigments ground into oil and used for decoration and widely used in the decoration of wallpaper.

From about 1860, following the prosperity associated with gold discovery, white lead and red lead were imported into the various colonies and Brunswick Green which is a pigment largely composed of lead chromate was imported from about.1880.

Between 1880 and the 1940s quite a few- suburbs of weatherboard homes had cream paint on the exterior walls (which was white lead containing both lemon chrome and yellow ochre) and the trim work on windows and verandahs was a shade of Brunswick Green).

From this period until 1945 white lead was used extensively for application:

a) In conjunction with red lead as "pink primer" for most timber.
b) it was used in the undercoat, which was applied to most timber both indoor and outdoor. It was also applied as the priming coat to trowelled plaster walls (lath and plaster) and to cement rendered surfaces.
c) Used for the exterior paint, top coats on weatherboards so that it may be said for these older homes the presence of white lead may be expected on any surface.

In addition there are the greens based on lead chrome, the Brunswick Green which was mentioned above and the primrose chromes, lemon chromes, oranges and Chinese red shades which were used in enamels. A very popular colour during the 1930s was called alternatively Nile Green or Eau De Nil for interior enamel work.

It was only after 1953 that in consequence of the legislation in Queensland, a general awareness of the desirability in certain locations of a lead free paint became widespread. However, until the 1960s there was quite a loose interpretation of the phrase "lead free". That is to say that a number of firms marketed flat oil paints which did not contain any white lead and therefore were referred to as a lead free range of paints, but which indeed

used lemon chrome and Brunswick Green for reaching some of the pastel colours. In the 1953 to 1960 period a number of enamels were marketed as lead free but did contain certain colours (such as golden yellow and orange and post office red) which were indeed based on coloured lead pigments. (Such colours were of course marked as lead-based on the labels.)

SUMMARY

There is some possibility that the age of a house can give a guide to the amount of lead pigments in the aged paint remaining on its surfaces and this will be seen by the discourse above. However, the same cannot be said for public buildings nor for factory buildings nor other structures which have been excluded from the ambit of the Uniform Paint Schedule.

Therefore, the people involved in long term exposure because of their employment in painting and coating have a problem with identification of the lead burden.

It is for this reason that we promote the motion which we moved at our second meeting that the working group should regard as its first priority the establishment of suitable test methods and procedures and education about these and at the same time should encourage or urge the government of NSW to bring in legislation which removes in NSW the possibility for putting lead paints onto industrial premises, or fabrications.

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First Published by BCCA on 28th April 1998. BCCA contact details revised 23rd January 2006.

1.5.2 Brief History of the Use of Lead in Cosmetics and Toiletries

Some of the lead compounds that are listed in TABLE 1 also occur in a worldwide distribution of cosmetics and therapeutics, both of the modern day type and of traditional products that are still in use in many under-developed countries today. The chemical might be labelled on the packaging of the product as either a branding/ naming that is equivalent to the product's main constituent, (e.g. "litargirio", a branding of the actual product whose product name is also the name of the main chemical), or else is labelled on the packaging as part of an entire list amongst the product's other ingredients. Sometimes due to the lack of universally expressible, recognisable identification of contents featuring upon the traditional type cosmetic and/or therapeutic product's packaging, the presence of lead in the traditional product may often go unnoticed or become obscured, and its importation, circulation, manufacture, and safe application may thus evade modern regulatory control. This is why it will be important to first list the common names by which traditional cosmetics and therapeutics are known, and to then list the chemical contents occurring in such products.

"Certain racial/ethnic populations at risk for lead exposure through use of traditional or folk remedies might fail to disclose use of these products when asked about use of "traditional or folk remedies," rather than by product name." In this report a lady repeatedly denied use of a "traditional or folk remedy", because she considered the substance to be of the nature of an ordinary everyday product (i.e. a deodorant) that was equivalent to any other on the market. She knew the product only by its branding, "litargirio," rather than recognising it as a chemical first, sold and distributed as a remedy that was actually prohibited. (Streamline, 2005).

On the other hand, cosmetics that are produced by modern-world manufacturers are more often than not packaged according to mandatory standard regulations, and thus the product's chemical constituents are listed according to mandatory standards, and under their more widely renowned English or INCI identification names. "The mandatory information standard requires that the names of the ingredients be either their English

names or their International Nomenclature Cosmetic Ingredient (INCI) names.)" (ACCC, 2000). This is according to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) Part 1 Interpretation, clauses v and viii, page 2 (NDPSC, 2005): " As permitted, there may also be an accompanying list in another language. (Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991, 6. Form of Ingredient List (2), page 6). In relation to a chemical that is either intended or not intended for therapeutic use, the ingredient at the very least should be labelled as the accepted scientific name or the name descriptive of the true nature and origin of the poison. For example, the listing of the content "lead acetate" in hair dyes as strictly the name "lead acetate" abides by modern classificatory systems, which adopts its Australian Approved Name in complicity with the Western Hazardous Substances Information System (HSIS) classification style. This type of naming is used as opposed to listing it on the packaging as a more obscure ingredient like "Goulard's powder", a synonym of lead acetate. The chemical constituents of a traditional cosmetic or therapeutic product may more widely reflect the product's ingredients according to the content's archaic or traditional type "classification", due to the product's culturally specific descriptive or traditional usage. It is for this reason that the following list represents the name of the cosmetic or therapeutic product first, before trying to classify its usage and identifying the possible chemical compounds that occur within them. This should also more accurately represent the cultural derivation and diverse range of usage of the product. As many of the chemical compounds found within these products correlate with compounds found in other products, the traditional name and its descriptive usage will also be listed first so as to avoid any repetitive overlapping of product names under various listings of different chemicals. This is because there are a widespread variety of chemical bases and compounds that occur commonly and/or together amongst all these products, whether or not they may even be related in location, cultural setting, or usage.

In this report the chemical lead acetate has been identified as the leading constituent of concern in modern cosmetics, which is present in modern world hair dyes and colour restorers at a level of 99%. In keeping with the above system, in this section this chemical will be listed under the heading "Progressive Hair Dyes". Lead compounds are also found

in a wide variety of colour additives, i.e. pigments that are manufactured in or imported by Western countries and then added as ingredients into the final composition of a modern day cosmetic product, like an eye-shadow, a mascara, and other types of cosmetics manufactured by the laboratories of many different leading brands. The different colour identification names of such pigments, and their various applications, will also be covered under the heading "EU/US/AU Colour additives".

1.6 Lead Compounds Currently Used in Surface Coatings/Inks in Australia, and their HSIS Classification

The lead compounds and their Chemical Abstracts Service numbers (CAS Nos) in TABLE 1 below were derived from the Chemical Gazette of January 2006 (Commonwealth of Australia, 2006) through the NICNAS survey of members of the Australian Paint Manufacturers Federation (APMF). The Hazardous Substances Information System (HSIS) classification search results on these lead compounds were found on the website of the Australian Safety and Compensation Council (ASCC, 2005). TABLES 2-4 provide the keys to interpreting the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (CHIP) symbols in TABLE 1 and are extracted from the Health and Safety Executive website in the United Kingdom. (HSE, 2005).

According to George Thomas of the Office of the Australian Safety and Compensation Council (ASCC): "The risk phrase numbers in the range 50 to 59 relate to environmental hazard classifications. The [Australian] National Model Regulations for Control of Workplace Hazardous Substances only require classification and subsequent labelling of health hazard effects. The environmental classification information is provided in HSIS (and previously the List of Designated Hazardous Substances) and the Approved Criteria for information purposes only. Because environmental hazards are not a mandatory part of the workplace hazardous substances regulatory framework in Australia, concentration cut-offs have never been specified in the List (or HSIS).

"In the EU, a preparation containing a substance classified as N: R50-53 would be classifiable when the substance is present above a concentration of 0.25%. [See TABLE 5 below]. Note that these classifications and risk phrases are not a mandatory requirement under the Australian workplace hazardous substances framework." (Thomas, 2006)

TABLE 5 provides the concentration limits to be used for the evaluation of environmental hazards and are extracted from the official journal of the European Communities (European Parliament and Council of The European Communities, 1999). Because TABLES 2-5 are required to interpret the symbols in TABLE 1 for each compound, TABLE 6 presents an example of the upshot of HSIS Classification for one lead compound (lead acetate) in the occupational setting.

In TABLE 1 below, for substances ascribed **Note E**, the Risk Phrases R20, R21, R22, R23, R24, R25, R26, R27, R28, R39, R68 (harmful), R48 and R65 and all combinations of these Risk Phrases should be preceded by the word 'also'.
Examples:
R23: 'also toxic by inhalation'.
R27/28: 'also very toxic in contact with skin and if swallowed' (ASCC, 2004)

TABLE 1 Lead Compounds Currently Used in Surface Coatings/Inks in Australia, and their HSIS Classification

CHEMICAL NAME	CAS NUMBER	LABELLING	HSIS CLASSIFI-CATION	CUT-OFFS
Lead acetate	301-04-2	T ; N ; R: 61 - 62 - 33 - 48/22 - 50/53, S: 53 - 45 - 60 - 61; Note: E	Repr. Cat.1; R61 Repr. Cat.3; R62 Xn; R48/22 R33 N; R50-53	Conc>=10%: T; R61; R62; R48/22; R33 >=5%Conc<10%: T; R61; R62; R33 >=1%Conc<5%: T; R61; R33

				>=0.5%Conc<1%: T; R61
Lead chromate molybdate sulfate red (Molybdate orange)	12656-85-8	T ; N ; R: 61 - 62 - 33 - 40 - 50/53, S: 53 - 45 - 60 – 61	Carc. Cat.3; R40 Repr. Cat.1; R61 Repr. Cat.3; R62 R33 N; R50-53	Conc>=5%: T; R61; R40; R62; R33 >=1%Conc<5%: T; R61; R40; R33 >=0.5%Conc<1%: T; R61
Lead sulfo-chromate (C.I. Pigment yellow 34)	1344-37-2			
* Lead compounds, with the exception of those elsewhere specified, that is:	Various	T ; N ; R: 61 - 62 - 20/22 - 33 - 50/53, S: 53 - 45 - 60 – 61	Repr. Cat.1; R61 Repr. Cat.3; R62 Xn; R20/22 R33 N; R50-53	Conc>=5%: T; R61; R62; R20/22; R33 >=1%Conc<5%: T; R61; R20/22; R33 >=0.5%Conc<1%: T; R61; R33
Lead monoxide	1317-36-8			
Lead sulfate	7446-14-2			
Lead molybdate	10190-55-3			
Lead chromate oxide	18454-12-1			
Lead octanoate	7319-86-0			
Lead 2-ethylhexanoate (Hexanoic acid, 2-ethyl-, lead(2+) SALT)	301-08-6			
Lead oxide	1317-36-8			

Lead nitrate	10099-74-8			
Lead naphthenate (Naphthenic acids, lead salts)	61790-14-5			
Lead peroxide (Lead dioxide)	1309-60-0			
Lead chrome 1244	Unknown			
Lead carbonate (white lead)	598-63-0			

TABLE 2 CHIP Symbol, Abbreviation/Description of Hazard Relevant to TABLE 1 Lead Compounds

Symbol (Health)	**Abbreviation**	**Hazard**	**Description of hazard**
	T	toxic	Chemicals that at low levels cause damage to health.
	Carc Cat 1	category 1 carcinogens	Chemicals that may cause cancer or increase its incidence.
	Carc Cat 2	category 2 carcinogens	
	Carc Cat 3	category 3 carcinogens	

	Repr Cat 1	category 1 reproductive toxins	Chemicals that produce or increase the incidence of non-heritable effects in progeny and/or an impairment in reproductive functions or capacity.
	Repr Cat 2	category 2 reproductive toxins	
	Repr Cat 3	category 3 reproductive toxins	
	Xn	harmful	Chemicals that may cause damage to health.
(Environmental)			
	N	dangerous for the environment	Chemicals that may present an immediate or delayed danger to one or more components of the environment

(HSE, 2005)

TABLE 3 CHIP Risk Phrases Relevant to TABLE 1 Lead Compounds

R20/22	Harmful by inhalation and if swallowed
R33	Danger of cumulative effects
R40	Limited evidence of a carcinogenic effect
R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed
R50	Very toxic to aquatic organisms

R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R51	Toxic to aquatic organisms
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R52	Harmful to aquatic organisms
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R53	May cause long-term adverse effects in the aquatic environment
R61	May cause harm to the unborn child
R62	Possible risk of impaired fertility

(HSE, 2005)

TABLE 4 CHIP Safety Phrases Relevant to TABLE 1 Lead Compounds

S45	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
S53	Avoid exposure – obtain special instructions before use
S60	This material and its container must be disposed of as hazardous waste

S61	Avoid release to the environment. Refer to special instructions/safety data sheet

European Communities Classifications for Aquatic Toxicity and Long-term Adverse Effects

The concentration limits fixed in TABLE 5 below, expressed as a weight/weight percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

TABLE 5 European Communities Classifications for Aquatic Toxicity and Long-term Adverse Effects

Classification of the substance	Classification of the preparation		
	N, R50-53	N, R51- 53	R52-53
N, R50 – 53	Cn ≥25%	2.5% ≤ Cn <25%	0.25% ≤ Cn <2.5%

(European Parliament and Council of The European Communities, 1999)

In TABLE 5, substances, such as all the lead compounds in TABLE 1 above, that are indicated as N (dangerous for the environment) and assigned risk phrases in the range R50-53, exert different aquatic toxicity and adverse environmental effects according to their classification of preparation, which is dependent on the concentration of the substance in the preparation. The following labelling should be applied:

- If the concentration of the substance classified as N, R 50-53 is more than or equal to 25%, then the preparation is classified as N, R50-53 and the labelling required on the preparation in European Communities would be N, R50/53.
- If the concentration of the substance classified as N, R 50-53 is between 2.5 and 25%, then the preparation is classified as N, R51-53 and the labelling required on the preparation would be N, R51/53.

- If the concentration of the substance is between 0.25 and 2.5%, then the preparation is classified as N, R52-53 and the labelling required on the preparation would be N, R52/53.

TABLE 6 Labelling Implications of HSIS Classification for Lead Acetate

HSIS Categorisation	Repr Cat 1	category 1 reproductive toxins	Chemicals that produce or increase the incidence of non-heritable effects in progeny and/or an impairment in reproductive functions or capacity
	Repr Cat 3	category 3 reproductive toxins	Chemicals that produce or increase the incidence of non-heritable effects in progeny and/or an impairment in reproductive functions or capacity
	Xn	Harmful	Chemicals that may cause damage to health
	N	dangerous for the environment	Chemicals that may present an immediate or delayed danger to one or more components of the environment
Safety Labelling Required in Australian Occupational Settings	S45	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)	
	S53	Avoid exposure - obtain special instructions before use	
	S60	This material and its container must be disposed of as hazardous waste	
	S61	Avoid release to the environment. Refer to special instructions/safety data sheet	

Risk Labelling Required in Australian Occupational Settings	>=0.5% Conc <1%	If the concentration is greater than or equal to 0.5 and less than 1%	T	Toxic	Chemicals that at low levels cause damage to health.
			R61	May cause harm to the unborn child	
	>=1% Conc <5%	If the concentration is greater than or equal to 1 and less than 5%	[In addition to the above two risk phrases:]		
			R33	Danger of cumulative effects	
	>=5% Conc <10%	If the concentration is greater than or equal to 5 and less than 10%	[In addition to the above three risk phrases:]		
			R62	Possible risk of impaired fertility	
	Conc >=10%	If the concentration is equal to or greater than 10%	[In addition to the above four risk phrases:]		
			R48/22	Also harmful: danger of serious damage to health by prolonged exposure if swallowed	
Environmental Labelling Required in European Communities	>=0.25% Conc <2.5%	If the concentration is greater than or equal to 0.25% and less than 2.5%	R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	

	>=2.5% Conc <25%	If the concentration is greater than or equal to 2.5% and less than 25%	R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
	Conc >=25%	If the concentration is greater than or equal to 25%	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

1.7 Lead Compounds Possibly Found in Cosmetics and Toiletries Currently Used in Australia, and their HSIS Classification

The lead compounds in TABLE 7 below, are derived from Section 1.5.2 and Section 1.8 of the current report and are by no means definitely found in cosmetic products in use in Australia today. The fact that some have unknown CAS numbers and no Material Safety Data Sheet (MSDS) is an indicator that they may only have been found in cosmetics historically.

TABLE 7 Lead Compounds Possibly Found in Cosmetics and Toiletries Currently Used in Australia, and their HSIS Classification

CHEMICAL NAME	CAS NUMBER	LABELLING	HSIS CLASSIFICATION	CUT-OFFS
Lead acetate	301-04-2	T ; N ; R: 61 - 62 - 33 - 48/22 -	Repr. Cat.1; R61 Repr. Cat.3; R62	Conc>=10%: T; R61; R62; R48/22; R33

		50/53, S: 53 - 45 - 60 - 61; Note: E	Xn; R48/22 R33 N; R50-53	>=5%Conc<10%: T; R61; R62; R33 >=1%Conc<5%: T; R61; R33 >=0.5%Conc<1%: T; R61
* Lead compounds, with the exception of those elsewhere specified, that is:	Various	T ; N ; R: 61 - 62 - 20/22 - 33 - 50/53, S: 53 - 45 - 60 – 61	Repr. Cat.1; R61 Repr. Cat.3; R62 Xn; R20/22 R33 N; R50-53	Conc>=5%: T; R61; R62; R20/22; R33 >=1%Conc<5%: T; R61; R20/22; R33 >=0.5%Conc<1%: T; R61; R33
Lead monoxide	1317-36-8			
Lead carbonate (white lead)	598-63-0			
Lead oxide	1317-36-8			
Lead sulfate	7446-14-2			
Lead sulphide	1314-87-0			
Lead hydrate	Unknown			
Lead chlorocarbonate	Unknown			
Lead chlor-hydroxide	Unknown			
Lead chloride	7758-95-4			

1.8 Cosmetic and Toiletry Products Known to Contain Lead Compounds

Exposure to lead through cosmetics and toiletry products can often go unnoticed due to the obscuration of the names of chemicals listed on the label. The following list of products has been ordered according to the product name so as to identify the extent to

which lead salts are used in cosmetic products both in Australia and throughout the world.

1.8.1 Litargirio

Origin of product use: Latin America (ECHO, 2005)

Chemical compounds: lead monoxide, lead (II) oxide (Streamline, 2005)

Chemical Synonyms: lead litharge, litharge, (Streamline, 2005), yellow lead oxide, masicot, Giallo Ossido di Piombo, Giallo di Piombo, oxido amarillo de plomo, plumbago (COSMOS ONLINE, 1995-2005), protoxide de plomb (European Commission, 2000)

Product synonyms: none

Appearance: yellow or peach coloured powder.(ECHO, 2005)

Uses: A traditional Dominican Republic remedy used as an antiperspirant / deodorant, a foot fungicide, a treatment for burns and wound healing, and for other cosmetic purposes. (ECHO, 2005)

Manufacture: Laboratory manufacture by Roldan, Ferreira, San Miguel, and others in Santo Domingo, Dominican Republic. Sold in cellophane and 2-inch by 3-inch clear packets. (LRC, 1997)

Hazard: content 79 % lead. (LRC, 1997) According to proposed modifications to the NICNAS Cosmetic Guidelines, anti-perspirants will now be classified as a cosmetic, not a therapeutic, and must therefore abide by future NICNAS regulatory conditions (NICNAS, 2005b). As a cosmetic, remedies may no longer be claimed under TGA authority (Newgreen, 2005).

1.8.2 Sindoor

Origin of product use: India

Chemical compounds: Red Lead

Chemical synonyms: lead tetraoxide, lead tetroxide, trilead tetraoxide, trilead tetroxide, lead oxide (3:4), lead oxide (III,IV), lead orthoplumbate, plumboplumbic oxide, C.I. 77578, C.I. pigment red, gold satinobre, heuconin 5, mennige, mineral orange, mineral red, minium, orange lead, Paris red, pigment red 105, red lead oxide, sandix, saturn red. (The Physical and Theoretical Chemistry Laboratory Oxford University (1995-2006) Product Synonyms: sindur, vermilion (Banglapedia, 2003), tilak, bindi, bindu, pottu, (Bakshi 2001), kumkum (synonym in the South), tumeric powder, vermillion, manjal, manjal kunkumam. (Banerjee 2005)

Uses: forehead marker on the spot between the eye-brows, a bodily location known in the Hindu and yoga traditions to be the seat of latent wisdom i.e. it is the “ajna chakra” (Bakshi, 2001).Current fashion trends have also made bindi application for the eyelids, eye corners, navel, nails, eyelashes, arms, neck, cheeks (Bakshi).Smeared along the parting of the hair (sithi) of Hindu women to signify mariage. (Banglapedia, 2003).

Appearance: reddish powder, also available in liquid form. (Banerjee, 2005)

Manufacture: No single method followed by manufacturers. Some mix oxidized metals and substandard oil to bring about the texture. Adding Rhodamine B dye may also be used to attain red sindoor colour. Red is also being derived from mercury sulphite. Branded sindoor, including those made by reputed cosmetic company Lakme, do not carry the mandatory label of ingredients. (Banerjee, 2005).

Hazards: Lead content up to 60 % (Lutolf 2004). Toxic ingredients trigger hair loss, edema and erythema. Addition of mercury sulphide can cause skin cancer. Addition of Rhodamine B dye can induce hereditary disorders. Sindoor can cause local irritation and

skin toxicity (as quoted by Tirtho Banerjee who himself quotes ex-Central Drug Research Institute scientist N. M. Khanna). Banerjee also states the following: “The nature of sindoor or kumkum can change with exposure to the environment over time and this can result in blisters, itching, rashes, pigmentation and, at times, serious dermatological disorders.”

1.8.3 Progressive Hair Dye

Origin of product use: Contemporary West

Chemical Compound: Lead acetate

Chemical Synonyms: Lead Acetate, Trihydrate; lead (II) acetate, trihydrate; acetic acid lead (II) salt, trihydrate; lead diacetate, trihydrate; Salt of Saturn; plumbous acetate; sugar of lead; Goulard's powder.

Product Synonyms: Hair colour restorer, hair colourer, hair dye, hair Creams, hair colouring shampoos and conditioners (Mielke).

Appearance: Lead acetate exists as colorless or white crystals, crystalline granules, or powders.

Uses: applied on hair over a period of time to achieve a gradual coloring effect. As the solution is rubbed on the hair, it penetrates the hair cuticle and the lead ions react with sulfur atoms in the proteins to form lead sulfide (PbS), which achieves a dark color. (quote?)
Lead acetate is also present in some oil free facial cleansers, such as those produced by Iman for people of colour (Skin Deep).

Hazardous Nature: may contain up to 10 times the limit allowed in house paint. Contains a chemical form that makes lead extremely bioavailable when ingested.Even

when used as directed, hair dye products containing lead acetate can coat hands with amounts of lead per hand between 150 and 700 mcg (Mielke). Surfaces that were touched by users of these products, or that came in contact with the products after application, were tested in a scientific study conducted by Howard Mielke (original article appearing in The Journal of American Pharmaceutical Association), and were often found to exceed 100 mcg of lead per square foot. By instructing users to coat their hands with a product that contains 2,300 to 6,000 mcg of lead per gram, an extremely large quantity of lead is placed directly into the hand-to-mouth pathway of exposure. The total Tolerable Daily Intake(3) (TTDI) for children is 6 mcg of lead and 30 mcg for adults, and in Mielke's results, the amount of lead on the hands increased from less than 3 mcg to between 150 and 700 mcg per hand after hair application. After applying the product and then thoroughly washing hands with soap and water, hands still retained from 26 mcg to nearly 80 mcg of lead per hand (Mielke). Some products specify that the product must remain on hair for an indefinite time in order to impart the colour. Users are also instructed to use some products daily until the desired colouring is obtained, and thereafter to continue use of the product twice every week. Ongoing, frequent use contributes to continuous lead contamination of the home environment, whereby surface lead residues accumulate over time. Users also sometimes directed not to shampoo for several days after application. Dry hands brushed through the dry hair treated with these products picked up between 70 and 286 mcg of lead per hand, amounting to about two to three times more lead than when wet hands are brushed through dry hair. An accidental spillage of even a 0.05 mL droplet of hair dye containing 2,000 mcg lead per gram in a small (120 mL or 4 oz) glass of water would contaminate the water by yielding a lead content of 833 mcg of lead per liter, many times over the acceptable U.S. drinking water standard of 15 mcg per liter (Mielke).

Labelling: Title 21 of the Code of Federal Regulations, section 73.2396) requires that the following caution statement appear on the product labels:

Caution: Contains lead acetate. For external use only. Keep this product out of children's reach. Do not use on cut or abraded scalp. If skin irritation develops, discontinue use. Do not use to color mustaches, eyelashes, eyebrows, or hair on parts of the body other than

the scalp. Do not get in eyes. Follow instructions carefully and wash hands thoroughly after use.(Center for Food Safety and Applied Nutrition; Office of Cosmetics and Colors Fact Sheet).
Prohibited import:
Description:
Cosmetic products containing more than 250mg/kg of lead except for products containing more than 250mg/kg of lead acetate designed for use in hair treatments.

1.8.4 Kohl

Origin of product use: Middle East; North Africa; Egypt; Morocco; Armenia; Oman; Afghanistan; Pakistan; India. (Vaishnav).

One of our listed examples includes the “Hashmi” brand and was founded by Hakim Mohammad Hasham in 1794 at Bareilly, India, and has since been manufactured in Pakistan, and sold worldwide: “Fascinated by the idea of alleviating the sufferings of the ailing humanity, the founder introduced Surma (KOHL) in the sub-continent, which is a unique medicament from eastern pharmacopoeia that has amazing curative and therapeutic properties for the eyes. Unique formulations exclusively prepared by our ancestors became well known all over the sub-continent for their curative and healing effect on the masses, thus the "HASHMI" brand became a household name in the sub-continent.”(Mohammad Hashim Tajir Surma, YEAR xxx enquiry has been emailed seeking year of publication). Other brands are also known to be commonly used in modern times in the Western world by immigrants, and everyday citizens.

Chemical Compounds: lead sulphide, lead sulphate, lead oxide, lead carbonate

Chemical Synonyms: black galena (PbS), anglesite (PbSO4), Cerrusite (PbCO3)

Product Synonyms: surma, guhlu, saoott, a-kohl, al-kahl, alkohl

Appearance: lead to silver gray, sometimes with a bluish tint. Kohl cosmetics are made in many ways, they may be powders that are applied using a brush/ moistened with oil or similar, solid forms of small lump on a stick to be moistened before application, stick form, or pencil/crayon with a soft interior (Danish Environmental Protection Agency, 2005).

Uses: traditionally derived women's adornment used to paint and outline the eyes, and still used worldwide today. Applied to infants' eyes, umbilical cord stump, and eyebrows. Intended to soothe, cleanse, beautify eyes, and protect them from disease. "For the protection and cleaning of eyes from dust and smoke, keeping the eyes cool & healthy, improve their appearance, gives relief to tired eyes due to excessive reading, computer and T.V use, gives strength to eyes, maintain eyesight and protects the eyes from various eye diseases" (Mohammad Hashim Tajir Surma, YEAR). The Danish Environmental Protection Agency conducted analyses into imported kohl products using information from TGD (2003), The Scientific Committee on Cosmetics and Non-Food Products (SCCNFP 2000) and a Dutch report on cosmetics. Assuming an average weight of approximately 3 grams per kohl product, an annual consumption of approximately 350 kg could be accounted for within Denmark. Furthermore, in the TGD (2003) and SCCNFP (2000) it is stated that eye liners are used 1 time daily at an amount of 5 mg each time. In the Dutch report it is assumed that kohl (eyeliner) is used 1 time daily by 10% of the population in amounts of 5 mg each time. The exposed skin area is calculated as a line over and under both eyes at a length of 4 cm and 2 mm wide, i.e. in total $4\times4\times0.2 = 3.2$ cm^2. Using a population in Denmark of 5.4 million inhabitants, the estimated yearly consumption is 5 mg 5.4×10^6 persons 0.1 (10%)×365 days = 986 kg. (Danish Environmental Protection Agency, 2005).

Manufacture: The lack of quality control, false or misleading claims on labels, presence of toxic metals and other contaminants in such traditional eye products is a problem of great concern (Vaishnav, 2001, page 46). Even "Present day commercial kohl, kajal, and surma preparations often contain dangerously high levels of lead and other toxins" (Cartwright-Jones, 2005, page 7). Hashmi Surma kohl is blended with processed Kohl

Stone, incorporated with amorphous black, Silver leaves, Zinc oxide, Ruby, Emerald, Turquoise, Pearls, Coral, Coral reef and herbs like Mumeera, Saffron, Neem & Chaksoo etc. (Mohammad Hashim Tajir Surma).

Labeling: Example of Hashmi Surma

Direction for use:
Clean the probe (Applicator) with the help of a clean dry cloth. Dip the Probe into the bottle and twist a little & shake. Take out the probe and tap it gently to remove the excess material and only a very fine film will remain on it. Apply the probe carefully at 180degree angle along the lower eyelid while closing the upper eyelid and softly slide out the probe by side ways up till its end. Clean the probe again with dry cloth prior to repeating the same procedure for the other eye.
Recommended Dose / Application:
Apply once during the day and once at bedtime or as suited.
Precaution:
Keep the product out of the reach of children. Do not use wooden probe. Do not use in case of excessive discharge, irritation or any other problem.
Warning:
For external use only.
Storage:
Store at room temperature. Protect from heat, light & moisture.
Best use within 5 years of manufacturing.
Made in Pakistan
(Mohammad Hashim Tajir Surma)

Lead content: According to the Danish Statutory Order on Cosmetics (Bkg. 489, 2003) lead must not be intentionally added in cosmetics. Lead was found in the main part of the analysed products above the detection limit of 0.05 µg/g; in 10 of those products the level ranged between 0.30 and 1 µg/g, and in 4 products between 1 and 4 µg/g. Lead was only found in a high concentration (280 mg/kg, or 280 µg/g) in one

product, and that particular product was manufactured in India. In this sample, the measured amount of 280 µg/g corresponds to approx. 0.028 % of the product (Danish Environmental Agency, 2006). “Thus lead was not found at concentrations above 0.028% in the kohl products but the highest concentration was measured in a product from India” (Danish Environmental Agency, 2006).
This study was particularly relevant to Danish legislation in the following ways: “The amendment to the Directive on cosmetics (Directive 2003/15/EC, EC 2003) prohibits the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1, 2 and 3, under Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, but allows the use of substances classified in category 3 pursuant to Directive 67/548/EEC subject to evaluation and approval by the SCCNFP” (Directive 2004/93/EC, EC2004).

Hazards: Undisclosed by many kohl companies is that the lead content in their products, according to E-medicine, can range from between 2.9 and 100% (Khan, 2005). In the study conducted by the Danish Environmental Protection Agency, Lead (Pb) occurred above the detection limit of 0.1 mg/kg in 15 out of 18 kohl products. The concentrations ranged from 0.3 to 280 mg/kg (Danish Environmental Protection Agency). In other studies, elevated blood lead levels found in Omani children was indicative of subclinical lead intoxication (Vaishnav, 2001, page 46). Use in neonates and in young children has been known to result in lead encephalopathy. An increase in the risk of trachoma in Saudi men who were kohl users has been documented, suggesting another risk includes transmission of various infections. (Vaishnav, 2001)
“These products should undergo quality control testing and toxicity studies. A rapid short-term toxicity screening method, as an adequate means to detect the toxic potential of an Indian traditional medication has been reported previously by the author. Uncontaminated and lead free eye cosmetics/medications that are safe to use should be marketed in India and overseas. Changes should also be made to the inadequate and misleading information found on the labels of such medications.” (Vaishnav, 2001, page

47). One site states that in the USA, kohl is defined as colour additive and not allowed to be used in cosmetics (Danish Environmental Protection Agency, 2005).However, it again states that sometimes products may use the name kohl without actually containing the prohibited ingredient kohl, and the FDA recommends the consumer carefully inspects the ingredients list.

1.8.5 Henna

Origin: Southern Europe, North Africa, the Middle East, parts of Asia. (DEPA), Indo-Pak subcontinent (Henna Sooq), Morocco (Maison Kenzi).

Chemical compounds: lead and lead compounds.

Chemical Synonyms: none found.

Product Synonyms: Black Henna, Henna rangs, harquu, mehndi, compound Henna dye (Cartwright-Jones), Instant Brown Henna (Henna Tribe).

Additive Synonyms: Henna extract, Colorless henna, Lawsonia alba extract, Lawsonia inermis extract, Neutral henna, Lawsonia inermis alba (NLM).

Appearance: Brown and Black coloured henna is used for skin staining and temporary tattooing; the more reddish coloured is used for temporary hair colouring (DEPA, 2005). Henna is distributed among powders, paste and shampoo. Found in ethnic stores and other health and general retail stores. There is a very large selection of shades but most are available in reddish brown nuances (DEPA, 2005). “Black Henna” mixes with PPD are usually dark brown or black. “Natural” Henna as a pure extraction does not contain lead and is a green plant powder that smells like hay and turns brownish or reddish after a few hours when mixed with water. Black Henna Indigo (not to be confused with Black Henna) is a green plant powder that turns blue in half an hour when mixed with water (Cartwright-Jones, 2005).

Use: used traditionally in the decoration of women in the form of tattoos or stains on the skin, and the colouring of fingernails (DEPA, 2005). Also used as a colourant for the hair (DEPA, 2005). Acts as a hair conditioner (smoothens hair cuticle by its sealing action), hair growth promoter, hair brightener and astringent (NRDC, YEAR xxx enquiry has been emailed seeking year of publication). Henna typically dyes the skin, or hair, an orange to cherry red and brown tone, and is available in either powder or paste form (Henna Sooq). In its natural form, Henna's dye component, hennotannic acid, does not pass through into the dermis; rather it stains the dead epidermal skin cells to naturally create brick/red/brown stains. Nuances of colour for the hair are normally limited to darker shades (DEPA, 2005). Harquu is a word for black facial ornamentation in North Africa and the Middle East, referring to both tattooing and skin painting. The patterns used across the different applications of harquus, tattooing, and henna often all mirror each other (Cartwright-Jones, 2005).

The grinded dry powdered plant parts of henna is used to colour the hair by mixing the powder with hot boiling water and stirring it into paste. After a certain cooling period the hot paste is massaged into the dry hair and skull of the head. Paste is left in hair for approximately 45 to 90 minutes before flushing / washing. Sometimes used with a special balsam for a following fixation of the colour to make it last longer. Hair colour lasts approximately 30 days (DEPA, 2005)

Manufacture: primarily extracted from plants of the genus Lawsonia. (Lawsonia inermis, also referred to as Lawsonia alba) (DEPA, 2005). Lawsonia is also said to be known as the “mignonette” plant (Henna Sooq). This henna plant is a small shrub that exists naturally in Western Asia and North Africa. The leaves are picked, dried and grinded into powdered henna (DEPA, 2005). The actual colouring agent in the henna leaves is called lawsone. In the series of henna products, some mixed products contain the ingredient p-phenylenediamine (CAS no. 106-50-3) and lawsone (2-hydroxy-1,4-naphthoquinone, CAS no. 83-72-7). The ingredient p-Phenylenediamine is used with an oxidation agent in oxidative based hair dyeing preparations (DEPA, 2005).

Ingredients: Harquu ingredients are isapropanol, ethanol, cellulose and cellulose derivatives, castor oil, Ultramarine Blue and Black Iron Oxide. (Mehandi.com).

Hazards: Lead (Pb) occurred in 10 out of 17 henna products analysed in the DEPA study at a range of between 0.5 to 2.0 mg/kg. The Scientific Committee on Cosmetics has also evaluated the additive para-phenylenediamine (PPD) to be a strong contact allergen. (DEPA, 2005). When PPD is used to make black temporary tattoos, often called "Black Henna", it can cause blistering, open sores, scarring, and lifelong health problems (Cartwright-Jones, 2005). A design that is applied with a black, inky looking paste that results in an immediate black stain is most likely to be a chemical hair dye passed off as "henna," rather than a powder made from a pure extraction of lawsonia from the henna plant, which is green, and turns reddish brown when mixed with water, and darkens on the skin over time. Such inks like PPD, a coal tar dye and known transdermal toxin, and other similar dyes, are found in leather and fur dyes as well as commercial hair dyes, and can cause itchy, oozing, blistering skin and long term scarring. In worse cases, organ damage can occur, along with permanent sensitization to even minute exposure to these dyes. It is a known carcinogen and is especially dangerous to pregnant or nursing women and children. Instant Brown Henna is another chemical dye, whose designs appear brown immediately without needing time for the reddish/brown colour to darken. (Henna Tribe).

1.8.6 Ceruse

Chemical Compounds: Lead carbonate and lead hydrate ($PbCO_3 + PbH_2O_2$)

Origin of product use: Ancient Greece, Ancient Rome (Bilezikian, 2004), Elizabethan Age (According to Leed, first used in 1521).

Synonyms: cerussite ($PbCO_3$), white galena, white lead, ceruse, calx of lead.

Appearance: colour is usually colorless or white, also gray, yellow, and even blue-green.

Product synonyms: venetian ceruse, ceruss

Uses: traditional skin whitener. The white pigment was used to lighten skin and enhance paleness (Bilezikian, 2004). Seems to have a waxy quality to it. Ancient Egyptian applications differ in that “white lead” was used to paint the eyes, and use as an eye-ointment. Used by Elizabethan women to cover face, neck, bosom, and often the hands and arms in conjuction with a 'skin firmer'- uncooked egg white. The combination was spread on the face, neck and bosom, and allowed to dry, to tighten, and hide wrinkles, and give the face a white, unlined, mask-like finish. It was eventually replaced in the nineteenth century with a powder made from zinc oxide. (Leed)

Manufacture: White lead doesn't occur in nature; rather, it is created by corroding lead with vinegar. (Seeking Ideal Beauty).

1.8.7 Galena

Chemical Name: Lead sulphide

Chemical Appearance: grey and relatively soft with a cubic crystal structure.

Origin of product use: Ancient Egypt. Important to list because Ancient Iranian, Mesopotamian, and Assyrian cultures all reflect similar formulas and uses for cosmetics, up until the modern day. Trade routes were established in ancient times that allowed for various cultures to take advantage of exclusive spices, oils, and extracts from neighbouring countries, so many similarities occur across these type of cosmetic formulas (Bilezikian, 2004). It is important to trace the usage of lead in Ancient Civilisations because “Cosmetic products used today in countries such as Egypt, Morocco, and Algeria mirror those used in the ancient empires of Egypt and Rome. This highlights the strong ties bonding modern Middle Eastern culture to its ancient history” (Bilezikian, 2004).

Product synonyms: see kohl.

Use: Used to colour eyelids.

Manufacture: Cartwright-Jones, commenting on the accounts of ancient historians, recreates the observations of Pliny and Discorides on galena manufacture: “galena was pounded with frankincense and gum, and then mixed with goose fat. It was put in dough or cow dung and burned. The burning drove sulphur out of the galena to form lead oxide. This was quenched with milk, and then pounded in a mortar with rainwater. This was decanted several times and the finest powder was collected, dried, and divided into tablets. Each woman would pulverize these and keep them in her cosmetic jar for application (2005).”Galena oxidizes upon heating, and it is supposed that this technique was used by Ancient Egyptians to produce shades of yellow and blue used around eyes. It is this very same technology that is used in modern-day cosmetic mineral labs to create ultramarine pigments from kaolin clay (Bilezikian, 2004).

1.8.8 White Face Pigments

Chemical Names: Lead Chlorocarbonate, Lead Chlor-Hydroxide, Lead Chloride

Chemical Synonyms: phosgenite ($Pb_2Cl_2CO_3$), laurionite (PbOHCl),
cotunnite ($PbCl_2$)

Origin of product use: Ancient Egypt.

Product Synonyms: see kohl. This traditional white face paint might also be referred to as a white type of “kohl” in both traditional and modern sources, although the constituents of “kohl” as outlined previously contains different lead elements when used as the silver-grey/ black make-up application for eyes.

Product Appearance: white powders.

Product Use: used to paint face. White pigments could have otherwise been obtained by white lead (see ceruse), since white cerussite PbCO3 could have been enough of an ingredient to vary and tune the cosmetics tint from black to white. However, these white lead derivatives, PbOHCl and Pb2Cl2CO3, were exclusively sought and synthesized, added to black PbS probably due to the way "cosmetics have been intensively used not only for aesthetic purposes, but also for their therapeutic and magic or religious properties. The Greco-Roman texts mention that the white precipitates synthesized from PbO are good for eye and skin care." (Martinetto, P. (1999), page 11). Cerusse was also used by Ancient Egyptians but instead to paint the face, rather than lighten or whiten the skin.

Manufacture: Both of these unique compounds, laurionite and phosgenite, can form from mixtures of smelted lead oxides in the presence of carbonate and salt water. According to ancient recipes, crushed purified silver foam (PbO) was mixed with rock salt and sometimes with natron (Na2Co3). This mixture was filtered and the procedure was repeated daily for several weeks. In modern experiments that replicate this procedure the resulting precipitate is successfully identified as laurionite. The same process in the presence of carbonate produces phosgenite. The mineral cotunnite was also yielded from samples of ancient Egyptian samples of cosmetic powders. (Martinetto (2001), page 3)

1.9 Overview of this Report

- ***Output 1*: Hazard Assessment**

a) A literature review into the hazards of the lead salts in TABLE 1 and TABLE 2 which are used in certain industrial surface coatings and inks, and cosmetics and toiletries including:

- Why the specified lead salts are hazardous.
- The adverse effects caused by exposure to lead based on the recorded assessments of health effects against the NOHSC *Approved Criteria for Classifying*

Hazardous Substances and the *Globally Harmonized System (GHS) for the Classification and Labelling of Chemicals.*

- The toxicity of lead as determined by reviewing human epidemiological and/or experimental animal data.

b) The problems and effects to health of lead in the specified products. [xxx – Research required to determine as we go along that the Hazard Assessment fulfils the promise of this overview of it]

***Output 2*: Risk management controls on use of lead in surface coatings and inks;** a review of regulatory and voluntary industry controls in Australia and overseas focusing on the following categories:

- Manufacturing / Importation:

regulations put in place to determine the amount of lead legally allowed in the various products.

occupational health and safety measures put in place to protect Australian workers from exposure to lead compounds. This will include such measures as protective gear and air circulation.

- Transportation:

how lead compounds are transported to the factory, and how the products containing lead are then transported from the factory including the Federal Office of Road Safety, *Australian Code for the Transport of Dangerous Goods by Road and Rail*, 6th Edition as well as information and controls from the United Nations Committee of Experts on the Transport of Dangerous Goods.

- Using / Handling:

controls currently in place for people using lead-based surface coatings and inks, including a comparison between regulations for industrial uses and those for public uses

issues of maintenance and application, particularly in regard to lead-based paints.

- Storing:

regulations put in place in regard to labeling products containing lead, including an examination of the regulations relating to containers used to store these products and warning labels required.

- Disposal / Removal:

regulations and/or warnings currently in place to ensure the safe disposal and/or removal of surface coatings containing lead.

[xxx – Research required to determine as we go along that the Regulatory Controls and Voluntary Industry Controls on Lead in Surface Coatings and Inks sections fulfill the promise of this overview of them]

***Output 3*: Risk management controls on use of lead in cosmetics and toiletries**; a review of regulatory and industry controls in Australia and overseas focusing on the following categories:

- Manufacturing / Importation:

regulations put in place to determine the amount of lead legally allowed in the products

occupational health and safety measures put in place to protect Australian workers from exposure to lead compounds. This will include such measures as protective gear and air circulation.

- Transportation:

how cosmetic products containing lead are transported from the factory to the retail stores.

- Using / Handling:

comprehensive review of current national and international regulatory controls put in place to prevent public exposure to lead compounds used in cosmetics

- Storing:

regulations put in place in regards to labeling cosmetics and toiletries containing lead.

examination of the containers used to store these products.

- Disposal:

regulations currently in place to ensure the safe disposal of cosmetic products containing lead.

[xxx – Research required to determine as we go along that the Regulatory Controls and Voluntary Industry Controls on Lead in Cosmetics and Toiletries sections fulfill the promise of this overview of them]

***Output 4*: Risk Management Report;** where the results from outputs 1-3 are drawn together in a final report. The report details the hazards of lead and the regulatory and voluntary industry controls in Australia and overseas to reduce public and occupational exposure during use of lead in surface coatings, inks and in cosmetics and toiletries. The report will be used to conduct a full risk assessment by NICNAS of lead salts used in surface coatings and inks and in cosmetics and toiletries and is expected to result in further regulatory action to minimize exposure to these products in Australia.
[xxx – Editing / Research required to draw together the final report and ensure it hangs together well, has consistent formatting and style, complies with the NICNAS Style Guidelines and that nothing is missing or wrong.]

For the purposes of this report:

- "surface coatings" refer to any paint products containing lead compounds including; car and marine primers and topcoats, steel and iron primers, whitegoods coatings, mirror backing paints, industrial paints and road marking paints;
- "inks" include older typesets and plates as well as roller coating, flexographic and screen inks for packaging;
- "cosmetics" refer to any product used to beautify the human body with such examples as eye-pencils and hair dyes.

As the project brief specified hazards as being health hazards, environmental concerns are not addressed in this report. (NICNAS, 2005c)

SECTION ONE REFERENCES

- ASCC (Office of Australian Safety and Compensation Council) (2004) Notes, Abbreviations and Notations. Guidance Material for the Hazardous Substances Information System- Hazardous Substances Data Set. <http://www.nohsc.gov.au/applications/hsis/HSGuidance.htm> Accessed 2006 Mar 3.
- ASCC (Office of Australian Safety and Compensation Council) (2005) Search for Hazardous Substances, Australian Government, Department of Employment and Workplace Relations. Search Hazardous Substance. <http://www.nohsc.gov.au/applications/hsis/searchhs.aspx> Accessed 2006 Jan 16.
- BAKSHI, Juhi (2001), "Bindi Emerges as a Fashion Statement", The Tribune (Online Edition), The Tribune House (publisher), JAISINGH, Hari (Editor),. for The Tribune Trust, 2001, Chandigarh, India, (October 31 2001), <http://www.tribuneindia.com/2001/20011031/main8.htm> Accessed 2006 Jan 15
- BANERJEE, Tirtho (2004), "The Hazards of Synthetic Sindoor", Hinduism Today, Himalayan Academy (publisher), 2004Lucknow, India, October/November/December 2004, <http://www.hinduismtoday.com/archives/2004/10-12/60-61_sindoor.shtml> Accessed 2006 Jan 11.
- BANGLAPEDIA (2003), ed. Sajahan Miah (ed.) Sirajul (ed.) ,"Sindur", Asiatic society of Bangladesh, ,http://banglapedia.search.com.bd/HT/S_0397.htm Accessed 2006 Feb 23
- Bilezikian, Debbie, Monave Mineral Cosmetics (2004), "Handmade Cosmetics in Ancient Times", All Natural Info, Allnaturalbeuty, Publisher Ambrosia, September 2004, <http://allnaturalbeauty.us/ani8.htm> Accessed 2006 Feb 24

- Cartwright-Jones, Catherine, “Harquus”, (2002, 2004, 2005) <http://www.harquus.com/> Accessed 2006 Feb 24
- CARTWRIGHT-JONES, Catherine, “Kohl as traditional women’s adornment in North Africa and the Middle East”, Introduction to Harquus: Part 2: Kohl, Tapdancing Lizard Publications, 2005, available at <http://www.hennapage.com/harquuspdfs/kohlintro.pdf>
- CCC (Australian Competition and Consumer Commission) (2000), Product Information A mandatory Guide: Cosmetics & Toiletries – ingredient labelling <http://www.accc.gov.au/content/item.phtml?itemId=323594&nodeId=file4230f150a2910&fn=Product%20safety%20guide%20-%20cosmetics%20and%20toiletries.pdf> Accessed 2006 Jan 8.
- Center for Food Safety and Applied Nutrition; Office of Cosmetics and Colors Fact Sheet, “Lead Acetate in Hair Dye Products”, U. S. Food and Drug Administration (January 9, 2002), <http://vm.cfsan.fda.gov/~dms/cos-lead.html>
- Commonwealth of Australia (2006) Declaration of Lead Compounds Used in Surface Coatings & Inks as Priority Existing Chemicals, in Section 2, pp 10-13, Chemical Gazette, No. C 01, 3 January 2006 <www.nicnas.gov.au/Publications/Chemical_Gazette/pdf/2006jan_whole.pdf> Accessed 2006 Jan 31.
- Cosmos Online (1995-2005), “Página del producto: LITARGIRIO AMARILLO (Masicot, Oxido de plomo amarillo, Oxido plumboso)”, Mexico, <http://www.cosmos.com.mx/pqs/____4g38.htm> Accessed 2006 Feb 23.
- Danish Environmental Protection Agency (2006), “Survey of chemical substances in kohl and henna products”, <http://www.mst.dk/homepage/default.asp?Sub=http://www.mst.dk/udgiv/publications/2005/87-7614-794-0/html/kap01_eng.htm>
- ECHO (Emergency and Community Health Outreach) (July 2005), Collaborative Association of Minnesota Counties (AMC), Minnesota Dangerous Lead Products (Ethnic Cultures), <http://www.echominnesota.org/QA/show11/danger.pdf> Accessed 2006 Jan 8.

- European Commission- European Chemicals Bureau, (2000) "IUCLID DATASET" (18 Feb 2000), <http://ecb.jrc.it/IUCLID-Data-Sheet/1317368.pdf> Accessed 2006 23 Feb
- European Parliament and Council of The European Communities (1999) DIRECTIVE of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labeling of dangerous preparations, Official Journal of the European Communities 30.7.1999 <http://ecb.jrc.it/LEGISLATION/1999L0045EC.pdf> Accessed 2006 Mar 3.
- Francis R (2000) ACA Presents Victor Nightingall Award [to John Hartley] in News, Journal of Protective Coatings and Linings, April 2000 <http:// www.paintsquare.com/library/view_article.cfm?articleID=181&CFID=271894&CFTOKEN=e9cfad14f4a67da6-7B37DADB-9E0A-7CD0-962E60B37B8F4BB9> Accessed 2006 Feb 18.
- Henna Sooq, Montreal, Quebec, Canada, (2005-2006), <http://www.hennasooq.com> Accessed 2006 Feb 24
- Henna Tribe (2004), Published by Kenzi et. al., (September 2004) <http://www.hennatribe.com/ppd.php> Accessed 2006 Feb 24
- Hirokawa, D., "Ancient Egyptian cosmetics and chemistry" (12 Feb 1999), News in Science, Published by The Australian Broadcasting Corporation (ABC), (2006), <http://www.abc.net.au/science/news/stories/s18834.htm>
- HSE (Health and Safety Executive) UK. (2005). List of symbols, abbreviations, risk and safety phrases. <http://www.hse.gov.uk/chip/phrases.htm> Accessed 2006 Feb 28.
- Kenzi, Maison, "Black Henna: The Facts, The Truth, The Warnings," Henna by Kenzi: Modern Mystical Adornment, (2001-2006), <http://www.kenzi.com/HENNA/HTML/warning.htm> Accessed 2006 Feb 24
- KHAN, Ali Nawaz, et. al., "Lead Poisoning", E-Medicine, (June 1, 2005), <http://www.emedicine.com/radio/topic386.htm>

- Leed, Drea (1996-2000), “Elizabethan Make-up 101”, The Elizabethan Costuming Page, <http://costume.dm.net/makeup.html> Accessed 2006 Feb 23
- LRC (NSW Lead Reference Centre) (1997) Possible Lead Containing Home Remedies and Cosmetics, awareness chart compiled by LRC using information from “Lead is a Silent Hazard”, pp 154-156 by Richard M Stapleton published by Walker and Company, New York 1994. http://www.oregon.gov/DHS/ph/lead/docs/homeremedies.pdf
- LUTOLF, Colleen, “Poisoning case leads to warning Family used powder meant for religious rite in food preparation”, (April 21, 2004), Sentinel, Woodbridge, NJ, (2003-2006), <http://ws.gmnews.com/News/2004/0421/Front_Page/034.html>
- Martinetto, P., et al., (1999), “Cosmetic Recipes and Make-up Manufacturing in Ancient Egypt”, Experiments Reports, European Synchrotron Radiation Facility (ESFR) Newsletter, ed. Montserrat Capellas Espuny, (April 1999) <http://www.esrf.fr/info/science/newsletter/apr99/pdf/pages10to11.pdf > Accessed 2006 Feb 21.
- Martinetto, P., et. al, (2001), “Synchrotron X-ray micro-beam studies of ancient Egyptian make-up”, Nuclear Instruments and Methods in Physics Research B 181 (2001) pages 744-748, Publisher N.H. Elsevier, <http://www.esrf.fr/exp_facilities/ID22/publications/drako_simult_diff_fluo.pdf> Accessed 2006 Feb 21.
- Mehandi.com (Supplies for Hair and Body Art), “Harquus: a SAFE black temporary tattoo”, TapDancing Lizard LLC, Ohio, Published by Catherine Cartwright-Jones (2002, 2004, 2005), <http://www.mehandi.com/shop/harquus/> Accessed 2006 Feb 24.
- Mielke, Howard, et.al., (1997), “Lead Based Hair Products: Too Hazardous for Household Use”, Re-published 2 October 1997 by University of Wisconsin, (2006) <http://www.uwsp.edu/geo/courses/geog100/MielkeHairLead1.htm> Accessed 2006 Jan 11.
- Mohammad Hashim Tajir Surma, Karachi, Pakistan, product range available at <http://www.aboutd.com/hashmisurma/index.shtml> Accessed 2006 Feb15.

- National Library of Medicine- National Institute of Health, (May 12 2004), "Household Products Database" NLM (2004), Delima Associates (2004), <http://householdproducts.nlm.nih.gov/cgibin/household/brands?tbl=chem&id=952> Accessed 2006 Feb 24
- National Research Development Corporation (NRDC), 1953-2003, "Henna Based Hair Dye Powder", <http://www.nrdcindia.com/pages/henna.htm> Accessed 2006 Feb 2
- NDPSC (National Drugs and Poisons Schedule Committee) (2005) Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) No. 20 Published July 2005, Effective 1st June 2005. Available for purchase from <http://www.tga.gov.au/ndpsc/susdp.htm>. Accessed 2005 Dec 7th.
- Newgreen, David B (2005) Review of the Regulation of Products at the Interface Between Cosmetics and Therapeutic Goods (Draft for Comment), page 29, March 2005 <http://tga.health.gov.au/consult/2005/cosmeticrepdr.pdf> Accessed 2006 Feb 21.
- NICNAS (National Industrial Chemicals Notification and Assessment Scheme) (2005b) Regulation of Cosmetic Chemicals: Final Report and Recommendations, November 2005 <http://www.nicnas.gov.au/Cosmetics/Regulation_Cosmetic_Chemicals_Final_Report_PDF.pdf> Accessed 2006 Jan 8.
- NICNAS (National Industrial Chemicals Notification and Assessment Scheme) (2005a) The Australian Government Regulator of Industrial Chemicals <http://www.nicnas.gov.au/>. Accessed 2005 Nov 12.
- Parish, Lawrence A. MD and Witkowski, Joseph A. MD (2001) You've Come a Long Way Baby: A History of Cosmetic Lead Toxicity, Clinics in Dermatology, Volume 19, Issue 4, Pages 367-370, July 2001, Elsevier Science Incorporated. Available for purchase from <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11535375&dopt=Abstract> Accessed 2006 Jan 27.
- Skin Deep, (April 2005), a project of the Environmental Working Group, Published by the Environmental Working Group and EWG Action Fund (2006),

"Iman Oil Free Cleanser" product information available at <http://www.ewg.org/reports/skindeep2/report.php?type=PRODUCT&id=1000016727 > Accessed 2006 Jan 15

- Streamline (2005) "Lead Poisoning Associated with Use of Litargirio — Rhode Island, 2003", in Streamline, The Migrant Health News Source, Volume 11, Issue 2, Migrant Clinicians Network, April/March 2005, page 3 <http://www.migrantclinician.org/news/streamline/20050304_mcn_streamline.pdf> Accessed 2006 Jan 8.
- The Physical and Theoretical Chemistry Laboratory Oxford University (1995-2006), "Safety (MSDS) data for lead oxide, red", Department of Chemistry, University of Oxford, <http://ptcl.chem.ox.ac.uk/MSDS/LE/lead_oxide_red.html> Accessed 2006 Feb 23.
- Thomas, George (2006) *Personal Communication by email*: WHEN is label R50/53 required for lead acetate containing products? Office of the Australian Safety and Compensation Council (ASCC), Department of Employment and Workplace Relations. Date Sent: 2006 Feb 1.
- VAISHNAV, Ragini (2001) "An example of the Toxic Potential of Traditional Eyes Cosmetics", Indian Journal of Pharmacology (2001) Volume 33, pages 46-48 <http://medind.nic.in/ibi/t01/i1/ibit01i1p46.pdf.> Accessed 2006 Feb 23.

2. HAZARD ASSESSMENT

2.1 Health Effects and Impacts of Chronic Lead Exposure

Lead has been used by humans for almost 3 millennia and lead poisoning has been known for more than 2500 years (Hernberg, 2000). Lead poisoning can affect all age groups, but the incidence varies. The true extent of lead toxicity in Australia is not known due to limited data.

Lead is toxic to many organ systems, among them haemopoietic system (developing blood cells), the nervous system and the renal system (Landrigan, 1994). Lead-induced toxicity to the brain causes delayed development, diminished intelligence, and altered behaviour (Landrigan, 1994). The definition of lead toxicity has changed considerably: formerly it was believed that only high exposures causing encephalitis were significant, but now its believed that even low dose exposure can lead to neurotoxicity (Silbergeld, 1997).

Adult lead poisoning generally occurs due to occupational exposure or renovation or other lead-related hobbies. Lead exposure occurs in occupational settings such as manufacturing or use of paint, pigments, some cosmetics (e.g. inexpensive cosmetic jewelry, kohl, surma, some hair dyes and colourants), car radiators, solders and batteries (ATSDR, 2005).

An organic form of lead was added to gasoline until the 1980s and it was estimated that this contributed up to 90 percent of atmospheric lead. Car emissions are also responsible for the increase in environmental lead concentrations reported between the 1930s and 1960s (Fischbein, 1998). The introduction of non-leaded petrol has made a considerable difference in some countries, but 150 countries in the world were still yet to decide on this issue according to Gavaghan (published in 2002) and leaded petrol is still sold in

possibly 80 countries as at the International Lead Poisoning Awareness Day of 2005 on 20th October (LEAD Group, 2005).

Children are at the greatest risk of exposure due to living in houses with lead based paints, some cosmetics and also through some remedies which contain lead (ATSDR, 2005). An Australian pediatrician in 1897 was the first person to report lead poisoning due to lead based paints used on porches and doors (Hernberg, 2000). The American National Health and Nutrition Examination Survey (NHANES) in 1997 reported that 16.4% of children living in cities with more than a million people and in houses built before 1946 had elevated blood lead levels.

Principal routes of exposure are usually by inhalation of generated dust, ingestion and skin contact. Lead in large amounts can affect the blood, nervous system, heart, glands, immune system and digestive system. Anaemia may also occur. If untreated, muscles may become paralysed, and there is also the possibility of brain damage.

Symptoms include joint and muscle pain, weakness in the back of the forearm, the wrist and the shin muscles, headaches, dizziness, abdominal pain, diarrhoea or constipation, nausea, vomiting, appearance of a blue line on gums, sleep disturbance and a metallic taste in the mouth. The pressure in the brain may increase with high doses, and cause brain damage, coma, and death.

Early signs of lead poisoning include loss of appetite and weight, constipation, tiredness and irritability, headache and weakness. Later there may be vomiting, nervousness, and muscle pains in the arms and legs. Serious cases cause severe vomiting, in-coordination, stupor, permanent eye damage, high blood pressure, multiple nerve disorders resulting in paralysis and loss of reflexes, delirium, convulsions and coma. The kidneys may become irreversibly damaged, and the nervous system could become affected causing mental retardation, cerebral palsy, and jerks and seizures. Lead can cross the placenta, and cause miscarriage, stillbirths and birth defects. Exposure before birth can cause mental retardation, behavioural disorders and infant death. It can also cause reduced sex drive,

impotence, sterility and damage the sperm of males, increasing the potential for birth defects. According to the Division of Occupational Safety, Department of Labor, Commonwealth of Massachusetts, 1998: “lead can damage sperm and affect the sperm's ability to move. It can affect the number of sperm that is produced in the testes. These effects on sperm can harm a man's ability to father children and have been linked to miscarriages and birth defects in their partners.” The menstruation cycle can also be affected in women. Lead can accumulate in the skeleton for a very long time. It is important that worker exposure be kept at a minimum and that industries adhere to State and Federal Government guidelines on the handling of lead compounds.

2.1.1 Lead and Ageing

The United States is the one country in the world in which large-scale nation-wide blood lead studies on people of all ages - the National Health and Nutrition Examination Surveys (NHANES) - have been conducted repeatedly enough to enable conclusions to be drawn about population blood lead trends. Data gathered from studies in the United States such as NHANES and the Normative Aging Studies (NAS) has allowed U.S. researchers to examine the effects of lead exposure in ageing populations.

Blood lead levels have declined dramatically in the US in the last 30 years with 0.7% of the US population in the period 1999-2002 having a blood lead level above 10 µg/dL compared to 78% in 1976-1980 (Mahaffey, 1982; Muntner, 2005). An individual aged 80 in 2006 has had 50 years of elevated blood lead levels prior to 1976 with exposure to leaded petrol, leaded paint, plumbing lead and contaminated dust and soil. Results from epidemiological studies in the US indicate that there are deleterious health effects in the ageing population at blood levels well below 10 µg/dL. Absorption of lead by the body varies with dose, duration, nutritional status at exposure, genetic factors, ethnicity, smoking habits, alcohol consumption and personal hygiene. These variables may explain the inconsistent results from some relatively small studies and must be taken into account with interpretation of results.

Blood levels indicate recent exposure but as lead is stored in bone, measurements of bone lead using X-ray fluorescence are better indicators of cumulative exposure. Lead accumulates in those regions of bone undergoing the most active calcification at the time of exposure. During infancy and childhood, bone calcification is most active in trabecular bone (patella) whereas in adulthood, calcification occurs at sites of remodelling in cortical (tibia) and trabecular bone (Aufderheider, 1992). Bone lead levels from a group of non occupationally exposed middle aged and elderly males with blood lead of 6.2 µg/dL were 22.1 µg/g (tibia) and 31.9 µg/g (patella) Hu, 2001). Bone lead increases by 0.2 (patella) and 0.15 (tibia) µg/g per year up to the age of 55 and then rises by 0.83 (patella) and 0.69 (tibia) µg/g per year after 55 years (Lin, 2004). In a post mortem study of US community exposed individuals, the percentage of lead body burden present in the bones was 78% at age 20 years increasing to 96% at 80 years (Saltzman, 1990).

Males have higher blood and patella lead but there are smaller differences in tibia lead between males and females (Lin, 2004). Bone lead is released back into the blood at levels associated with bone turnover and account for a rise in blood lead levels with ageing. This is pronounced in postmenopausal women not on hormone replacement therapy. To assess the impact of lead on an ageing population, the first consideration is whether the individual was occupationally exposed in a primary lead industry or other metal working industries. Previously employed blue collar workers not exposed in a primary lead industry still had significant exposure with 6 times the level in tibia lead compared to those with ambient exposure. This is despite having mean blood lead levels of 6 µg/dL (Elmarsafawy, 2002,). Even at this level of blood lead, there are deleterious health effects. **Kidney disease** and **peripheral arterial disease** are associated with blood levels greater than 2.47 µg/dL in elderly men (Muntner, 2005). In a study of aged men with mean levels for blood lead of 6.5 µg/dL, patella lead of 32.4 µg/g and tibia lead of 21.5 µg/g, renal function was impaired in diabetics when tibia lead was in the high range of normal levels at around 34 µg/g. Coexisting hypertension had a similar effect (Tsaih, 2004). Direct associations between hypertension and blood lead levels are weak and but occur in some ethnic groups (Muntner, 2005).

Cognitive decline measured by MiniMental State examination (MMSE) was found in community based elderly men in the top quartile of normal range patella lead levels. The effect of a 20 µg/g increase in patella lead range on MMSE score was equivalent to ageing an additional 5 years The effect is not as pronounced with top quartile normal range tibia lead levels and absent with blood lead. (Weisskopf, 2004). Following occupational exposure, tibia lead predicts decline in tests of verbal memory and learning, visual memory, executive ability and manual dexterity. The effect of an increase of 15.7 µg/g in tibia lead on test decline was equivalent to ageing an additional 5 years (Schwartz, 2000).

Past studies have indicated that lead toxicity is associated with deficits in vitamin D metabolism, haem synthesis and osteoporosis. The more recent epidemiological work indicates that low dietary vitamin D intake increases both tibia and patella lead (Cheng, 1998). Variants in a haem synthesis enzyme delta-aminolevulinic acid dehydratase (ALAD) are associated with reduced blood and bone lead levels compared to wildtype ALAD alleles (Hu, 2001). There is no recent evidence to link bone lead levels with osteoporosis. On the contrary, osteoporosis releases lead from the bone and elevates blood lead levels. (Berlin, 1995). Occupational exposure is also regarded as a risk factor for prostate cancer (Siddiqui, 2002) but there is no conclusive evidence linking lead exposure with other forms of cancer.

There are fewer studies available for elderly females. Due to lead turnover during pregnancy and lactation, women who have had children have lower tibia lead levels than nulliparous women. Patella lead is not affected by parity (Korrick, 2002). In a Swedish community study with high numbers of elderly females, no association was found between cognitive function and blood lead (Nordberg, 2000). The findings in elderly males of deleterious effects associated with certain levels of patella lead may apply to women.

Lead levels in the ageing patient are additive to deteriorating health. Renal disease, peripheral arterial disease and cognitive decline are associated with blood lead

levels under 10 µg/dL. The impact of past lead exposure should be considered in patient management.

[xxx Research required –to improve this **Chronic Health Effects and Impacts of Lead** section using, *inter alia*, the following references:

- Lustberg M, Silbergeld E (2002) Blood lead levels and mortality. Arch Intern Med, 162:2443-2449.
- Stauding K, Roth V (1998) Occupational lead poisoning. Am Family Physician, 57(10):719.
- Landrigan P, Todd CA (1994) Lead poisoning .The Western Journal of Medicine, 161(7): 153.
- Gardella C (2001) Lead Exposure in Pregnancy: A Review of the Literature and Argument for Routine Prenatal Screening.O&G Survey 56(4):231-238.
- Seeber A, Meyer M, Schaper M (2002) A summary of two meta-analyses on neurobehavioural effects due to occupational lead exposure .Arch Toxicol, 76:137-145.
- Pocock SJ, Smith M, Baghurst P (1994) Environmental lead and children's intelligence: a systematic review of the epidemiological evidence.BMJ, 309:1189-1197.
- Nash D, Magder L, Lustberg M (2003) Blood Lead, Blood Pressure, and Hypertension Perimenopausal and Postmenopausal Women. JAMA, 289:1523-1532.
- Denham A, Collins L, Fashner J (2003) Is screening for lead poisoning justified. The Journal of Family Practice, 52(9):722-724.
- Perazella M (1996) Lead and the kidney: nephropathy, hypertension and gout. Connecticut Medicine, 60(9):521-6.
- Crewalk J, Shenot P, Rivas D (1996) Mixed urinary incontinence secondary to lead poisoning. Journal of urology, 155(6):2029.
- Freddie A, Williams Jr, Sandra Delrahim (1996) Blood lead levels in children in South Central Los Angeles. Archives of Environmental Health, 51(6):383.]

2.2 Inventory of Lead Compounds used in Inks, Surface Coatings, Cosmetics and Toiletries in Australia

The Australian Paint Manufacturers Federation (APMF) has recently embarked on a program which intends to eliminate lead from those surface coatings and inks in which its use is continued. NICNAS has taken note of this initiative and assisted the APMF in conducting a survey of ink manufacturers, surface coating manufacturers, and suppliers of lead compounds to the inks and surface coatings industry. Results from this survey have yielded the names of a number of lead compounds currently in use within the industry. These are detailed in TABLE 1 above. A similar survey of the Australian cosmetics industry is expected to provide further lead compounds but for now we know for certain that lead acetate is used in hair colour restorer formulations in Australia so lead acetate appears in TABLE 2 for this reason.

As the Hazard Assessment for *Output 1* involves identifying the hazards to health of the various lead salts, it is important to establish an inventory of these substances. Below I have attempted to outline the use, the health hazards, and the engineering controls which should be utilized in the work place to reduce the risk of exposure. Most of the information has been taken from ChemWatch, a commercially available database that provides technical information and Material Safety Data Sheets (MSDS) on hazardous substances. All the ChemWatch MSDS references are listed in the Section Two References at the end of this Section. Whenever a non-ChemWatch document has been quoted, you will see a bracketed ChemWatch citation before the other quote, and then a bracketed citation. [xxx Research required – we need to do more than summarise info from ChemWatch MSDSs here (below) – we should compare this info to other well-regarded MSDSs and / or to other well-regarded research publications on these lead salts]

2.2.1 **Lead monoxide**

CAS: 1317-36-8

Synonyms: PbO, Yellow Lead Oxide, Lead Mono oxide, Lead II oxide, plumbous oxide, C.I. Pigment Yellow 46, C.I. 77577, Lead protoxide, Lead Monooxide, Canary litharge, Yellow Lead Ochre, Massicot, Massicotite, BDH 10146, Merck 29040, CI Pigment Yellow 46, CI 77577

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, and in accordance with the Australian Dangerous Goods (ADG) Code, it is also classified as a dangerous good.

Uses: Used as a raw material for organic and inorganic lead salts manufacture, for such products as battery oxides, lead chromate pigments, naphthenates and octoates in paints and lubricants. It is also used in the manufacture of lead crystal, glass and pottery glazes, as well as a vulcanizing agent for rubber, particularly neoprene rubber. Archaically it was used in ointments.

Appearance: It is pale yellow / bright yellow orange coloured. It is a very dense and odourless powder. While it does not mix with water, Lead Monoxide is classed as "soluble" under the provisions of SP 199 of the ADG Transport Code. It is insoluble in alcohol, but soluble in acetic acid, dilute nitric acid, and warm alkali hydroxide solutions.

Health Hazards

Swallowed: While this is an unlikely occurrence in industrial and consumer use circumstances, if swallowed in large quantities the compound may be fatal. Ingestion may result in nausea, abdominal irritation, pain and vomiting.

Eye: The dust may be discomforting and may be abrasive and harmful following absorption through the eye. This is capable of causing a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage and ulceration.

Skin: The dust may be discomforting to the skin as it is slowly absorbed through the pores. Toxic effects may result from skin absorption. As such, bare unprotected skin should not be exposed to this material. The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.

Inhaled: The dust from this compound may be discomforting to the upper respiratory tract if inhaled. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. (ChemWatch, 2005a)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction. Exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace.
If in spite of local exhaust an adverse concentration of the substance in air could occur, respiratory protection should be considered. (ChemWatch, 2005a)

2.2.2 **Lead chromate**

CAS: 7758-97-6

Synonyms: PbCrO4, chromic acid lead salt, lead chromate (VI), Canary Chrome, Lemon Yellow, Primrose Chrome Green, C.I. 77600, lead chromate VI, CI 77600, CI Pigment Yellow 34 * (ChemWatch, 2005b)
* Note: In a Google search of Australian websites on 28th Dec 2005, there were no documents found which included the three phrases: "CI Pigment Yellow 34" "7758-97-6" "lead chromate". However, on the web generally, 160 documents included these three phrases so we conclude that the synonym CI Pigment Yellow 34 is commonly used overseas to mean Lead Chromate. See note for Lead Sulfo-Chromate synonyms in Section 2.2.5 of this report.

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, but in accordance with the ADG code it is classified as a non-dangerous good.

Uses: Lead Chromate is used in auto and machinery refinish paint and primers (EMD Chemicals Inc., 2004). A number of Australian paint manufacturing survey respondents indicated to NICNAS that it is still used and fairly extensively (Zaluzny, 2005). It has also been used as a pigment in plastics, printing ink, fabrics and for decorating china and porcelain (ChemWatch, 2005b).

Appearance: It is a yellow or orange-yellow powder, and is insoluble in water. It is also odourless and soluble in fixed alkali hydroxides and dilute solutions of nitric acid.

Health Hazards

Swallowed: Considered an unlikely event, if the material is swallowed it may be moderately discomforting and toxic. Ingestion may result in nausea, abdominal irritation, pain and vomiting.

Eye: The dust from lead chromate may be discomforting to the eyes and is capable of causing a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage and ulceration.

Skin: If exposure is prolonged then the material is moderately discomforting to the skin. Toxic effects may result from skin absorption, so open cuts, abraded or irritated skin should not be exposed to this material.

Inhaled: The dust may be highly discomforting to the upper respiratory tract and lungs if inhaled and is likely to be particularly harmful if exposure is prolonged. Lead chromate is capable of causing sneezing, rhinorrhoea (watery nose) and in extreme cases, lesions to the nasal septum. (ChemWatch, 2005b)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: Local exhaust ventilation is required in order to keep exposure levels below required standards.
[xxx – research required see TABLE 15.1 on page 128 at http://www.nicnas.gov.au/Publications/CAR/PEC/PEC23/PEC_23_Full_Report_PDF.pdf for an example of the type of TABLE required to compare exposure standards in Australia and other countries or just lead exposure standards if there are no specific standards for the various lead salts]
Where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction. As such, exhaust ventilation should be designed to prevent accumulation and encourage the recirculation of particulates in the workplace. It is possible that in spite of local exhaust an adverse concentration of the substance in the air could occur, so respiratory protection should be considered. (ChemWatch, 2005b)

2.2.3 **Lead sulphate**

CAS: 7446-14-2

Synonyms: PbSO4, sulfuric acid,lead (2+) salt (1:1), lead(II) sulfate (1:1), anglislite, bleisulfat, C.I. 77630, Fast White, Freeman's White Lead, Lead Bottoms, Milk White, Sulfate de Plomb, sulfuric acidlead 2, salt 11, leadII sulfate 11, CI 77630, Freemans White Lead

Uses: Lead sulphate is used as a replacement for white lead in pigment form. It is also used for the production of minum in lithography, in the preparation of quick-dry oil varnishes and for the weighting of fabrics.

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, and in accordance with the ADG Code, this is also classified as a dangerous good.

Appearance: It is a white, heavy crystalline powder. While it does mix with water, it is much more soluble in dilute hydrochloric or nitric acids.

Health Hazards

Swallowed: The material is moderately discomforting to the gastro-intestinal tract if it is swallowed. While sulfates are not well absorbed orally, it can still cause diarrhoea.

Eye: The dust may be discomforting to the eyes and is capable of causing a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage and ulceration.

Skin: Lead Sulphate may be mildly discomforting to the skin. Open cuts, abraded or irritated skin should not be exposed to this material as toxic effects may result from skin absorption.

Inhaled: The dust may be discomforting to the upper respiratory tract if inhaled. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate

are inhaled. Lead fumes are toxic and act as a cumulative poison [xxx research required – should a general statement be made about lead fumes in relation to all these salts or should the description of only specific salts mention lead fumes?]. Regular blood testing should be considered for workers who are continuously exposed. [xxx research required – shouldn't this statement be made in a general section at the beginning and related to the exposure standards?] (ChemWatch, 2002a)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: General exhaust should be adequate under normal operating conditions. Local exhaust ventilation may be required in specific circumstances. If risk of overexposure is apparent, workers should wear approved respirator. Correct fit is essential to obtain adequate protection. (ChemWatch, 2002a)

2.2.4 **Lead molybdate**

CAS: 10190-55-3

Synonyms: O4-Mo-Pb, lead molybdate(VI), molybdate orange, molybdic acid, lead salt

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, but in accordance with the ADG code it is classified as a non-dangerous good.

Uses: Lead Molybdate is used as a colour pigment, as a component of molydate orange.

Appearance: It is a yellow coloured powder. Lead Molybdate does not mix with water, but it is soluble in nitric acid.

Health Hazards

Swallowed: The material is moderately discomforting to the gastro-intestinal tract and may be harmful if swallowed in large quantities. Molybdenum, an essential trace element, can in large doses hamper growth and cause loss of appetite, listlessness and diarrhoea. Anaemia also occurs, along with other symptoms including the greying of hair, shrinking of the testicles, reduced fertility and milk production, shortness of breath, in-coordination and irritation of the mucous membranes. Symptoms of copper deficiency are also seen in some cases.

Eye: The dust may be discomforting to the eyes and is capable of causing a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage and ulceration.

Skin: The material is moderately discomforting to the skin and is capable of causing a skin reactions which may lead to dermatitis.

Inhaled: The dust may be discomforting to the upper respiratory tract and may be harmful if inhaled. Lead fumes are toxic and act as a cumulative poison. As such, regular blood testing should be considered for workers who are continuously exposed. Bronchial and alveolar exudates are apparent in animals exposed to molybdenum by inhalation. Molybdenum fumes may produce bronchial irritation and moderate fatty changes in the liver and the kidney. (ChemWatch, 2001a)

Chronic Health Effects: Along with the health effects caused by exposure to Lead, which are outlined in Section 2.1, Molybdenum compounds can also cause liver changes with elevated levels of enzymes while causing over-activity of the thyroid gland. A generalised feeling of unwellness can occur, with tiredness, weakness, diarrhoea, loss of appetite and weight. Molybdenum has also been associated with cancers of the airways and a low intake of molybdenum is thought to cause an increased risk of developing oesophageal cancer.

Engineering Controls: Ventilation should be adequate under normal conditions, however if risk of overexposure occurs, approved protective clothing should be worn. (ChemWatch, 2001a)

2.2.5 **Lead sulfo-chromate**

CAS: 1344-37-2

Synonyms: lead chrome (VI) Pale Primrose Lemon Chrome Yellow Light, C.I. 77603, C.I. Pigment Yellow 34 * also as C.I. 77600, Clariant Chrome, Yellow Y-933-LD 194735, Lemon Chrome Yellow - DCC 1026, 1032, 4032, 1036, 1039, 1040, Y-933-LD, Y-934-LD, Medium Chrome Yellow – DYM, lead chrome VI Pale Primrose, CI 77603, Clariant Chrome Yellow Y933LD 194735, Lemon Chrome Yellow DCC, Y934LD, Medium Chrome Yellow DYM (ChemWatch, 2003a)
* Note: In a Google search of Australian websites on 28th Dec 2005, there was one document (NICNAS, 2000) found which included the three phrases: “CI Pigment Yellow 34” “1344-37-2” “lead sulfochromate”. However, on the web generally, 78 documents included these three phrases so we conclude that the synonym CI Pigment Yellow 34 in Australia is used to mean Lead Sulfo-Chromate rather than Lead Chromate whereas overseas, it is twice as likely to be used to mean Lead Chromate. See note for Lead Chromate synonyms in Section 2.2.5 of this report.

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, and in accordance with the ADG Code, this is also classified as a dangerous good.

Uses: Lead Sulpho-Chromate is used as a colour pigment in paint and as an anti-corrosive pigment in primers. It is also utilized as a pigment in canvas fabrics and for decorating china and porcelain. In accordance with the Worksafe draft, 2002, sprayed coatings containing more than 1% Lead, or approx 2% lead sulpho chromate are defined as Toxic Spray Painting Substances.

Health Hazards

Swallowed: While considered an unlikely route of entry in industrial and consumer environments, if swallowed Lead Sulpho-Chromate is discomforting to the gastro-intestinal tract. Ingestion may result in nausea, abdominal irritation, pain and vomiting.

Eye: The dust is discomforting and may be abrasive to the eyes.

Skin: The material may be mildly discomforting to the skin. It is absorbed by the skin from repeated exposures over long periods and under such circumstances, may be harmful.

Inhaled: The dust may be discomforting to the upper respiratory tract if inhaled, particularly if exposure is prolonged. Respiratory sensitisation may result in allergic/asthma like responses; from coughing and minor breathing difficulties to bronchitis with wheezing, gasping. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. (ChemWatch, 2003a)

Chronic Health Effects: Along with the effects of lead outlined in Section 2.1, long term exposure to high dust concentrations may cause changes in lung function, resulting in such diagnosis as pneumoconiosis. This is caused by particles less than 0.5 micron penetrating and remaining in the lungs. Prime symptoms of this hazard are breathlessness and lung shadows which can be seen on an X-ray.

Engineering Controls: The material should be used in a well-ventilated area. Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction. The exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace. If, in spite of local exhaust, an adverse concentration of the substance in air could occur, respiratory protection should be

considered. The lead concentration in air is to be maintained so that the lead concentration in workers' blood remains below 0.060 mg/100 g of whole blood (Chemwatch, 2003a).

2.2.6 **Lead chromate molybdate sulfate red**

CAS: 12656-85-8 and 12709-98-7

Synonyms: Chrome Vermilion, C.I. Pigment red 104 – Molybdate Orange, C.I. Pigment Red 104, Krolor Orange RKO-104, Mineral Fibre Red 5DDS, Mineral Fire Red 5GS, Molybdate Orange Y-786-D, 5GS, YE-421-D, YE-698-D, Molybdate Red AA3, Molybdenum Red, NCI-C54626, Renol Molybdate Red RGS, Vynamon Scarlet BY, Kikuchi Thermo Orange KS-7000, Thermo Orange KS 7000, C.I. No. 77605, Molybdate Orange, Molly Orange, Moly Orange, CI Pigment Red 104, Krolor Orange RKO104, Molybdate Orange Y786D 5GS, YE421D, YE698D, NCIC54626, Kikuchi Thermo Orange KS7000, CI No 77605

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, but in accordance with the ADG code it is classified as a non-dangerous good.

Uses: Lead Chromate Molybdate Sulphate Red is used as an anti-corrosive pigment in industrial paints, plastics, printing inks and industrial finishes.

Appearance: It is an odourless orange powder that is insoluble in water.

Health Hazards

Swallowed: The material is moderately discomforting if swallowed and can do damage to the gastro-intestinal tract, particularly if ingested in large quantities. In large doses, Molybdenum, which is an essential trace element, can hamper growth and cause loss of appetite, listlessness and diarrhoea. Anaemia can also occurs, while other symptoms

include greying of hair, shrinking of the testicles, reduced fertility and milk production, shortness of breath, in-coordination and irritation of the mucous membranes. Symptoms of copper deficiency are also seen in the case of ingestion.

Eye: The dust may cause eye discomfort inducing smarting, pain and redness.

Skin: The compound is moderately discomforting to the skin and is capable of causing skin reactions which may lead to dermatitis.
Open cuts, abraded or irritated skin should not be exposed to this material.

Inhaled: The dust produced by this material may be discomforting to the upper respiratory tract and could be harmful if inhaled. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.
(ChemWatch, 2003b)

Chronic Health Effects: along with the health hazards caused by Lead as outlined in Section 2.1, Molybdenum compounds can also cause liver changes with elevated levels of enzymes, as well as causing over-activity of the thyroid gland. A generalised feeling of unwellness can occur, with tiredness, weakness, diarrhoea, loss of appetite and weight. Molybdenum has also been associated with cancers of the airways while a low intake of molybdenum may cause an increased risk of developing oesophageal cancer.

Engineering controls: Local exhaust ventilation may be required in order to keep exposure to workers below the required standards. In confined spaces where there is inadequate ventilation, full-face air supplied breathing apparatus should be worn. In addition to this, spraying must be carried out in conditions conforming to State Spray Painting Regulations. (ChemWatch, 2003b)

2.2.7 **Lead chromate oxide**

CAS: 18454-12-1

Synonyms: Pb2CrO5, lead chromate (VI) oxide, basic lead chromate, chrome orange 54 56 57 58, chrome orange g, chrome orange r, chrome orange rf, chrome orange xl, C.I.-77601, C.I. Pigment Orange 21

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, and in accordance with the ADG Code, this is also classified as a dangerous good.

Uses: The use of lead chromate oxide as a colour pigment in paint in obscelescent due to governmental restrictions. It has also been used as a pigment in plastics, printing ink, fabrics and for decorating china and porcelain.

Appearance: The material is a yellow or orange-yellow powder, which is insoluble in water. It is, however, soluble in fixed alkali hydroxides and dilute solutions of nitric acid. It is an odourless substance.

Health Hazards

Swallowed: The compound is moderately discomforting and toxic if swallowed. Ingestion may result in nausea, abdominal irritation, pain and vomiting.

Eye: The dust may be discomforting to the eyes and is capable of causing a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage and ulceration.

Skin: The material is moderately discomforting to the skin if exposure is prolonged. Toxic effects may result from skin absorption, so open cuts, abraded or irritated skin should not be exposed to this material.

Inhaled: The dust may be highly discomforting to the upper respiratory tract and lungs if inhaled, especially if exposure is prolonged. Inhalation of the compound is capable of causing sneezing, rhinorrhoea (watery nose) and in extreme cases, lesions of the nasal septum. (ChemWatch, 2001b)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: Local exhaust ventilation should be used to prevent accumulation and recirculation of particulates in the workplace. If, in spite of local exhaust, an adverse concentration of the substance in air continues to occur, respiratory protection should be considered. (ChemWatch, 2001b)

2.2.8 **Lead octanoate**

CAS: 7319-86-0

Synonyms: C16-H30-O4-Pb, Pb(C8-H15-O2)2, octanoic acid, lead(2+) salt, lead dioctanoate, lead(II) caprylate, lead(II) octoate, lead octonate, C16H30O4Pb, PbC8H15O22, octanoic acid lead2 salt, leadII caprylate, leadII octoate

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, and in accordance with the ADG Code, this is also classified as a dangerous good.

Uses: Lead Octanoate is used as a dryer for varnishes and lacquers. It is also used in high pressure lubricants, for lubricants in the extrusion process, as a stabiliser for vinyl polymers, and as a corrosion inhibitor for petroleum.

Appearance: The material appears as white flakes, and does not mix with water. It is, however, soluble in hot alcohol.

Health Hazards

Swallowed: The material is moderately discomforting to the gastro-intestinal tract and may be harmful if swallowed in large quantities.

Eye: The compound is moderately discomforting and has the capacity to cause a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage and ulceration.

Skin: The material is moderately discomforting to the skin and is capable of causing skin reactions which may lead to dermatitis. If the material mixes with moisture on the skin, such as perspiration, irritant effects may be increased.

Inhaled: If inhaled, the dust may be discomforting to the upper respiratory tract. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. (ChemWatch, 2004a)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: General exhaust is adequate under normal operating conditions, however local exhaust ventilation may be required in specific circumstances. If risk of overexposure exists, an approved respirator should be worn. Correct fit is essential to obtain adequate protection. (ChemWatch, 2004a)

2.2.9 **Lead 2-ethylexanoate**

CAS: 301-08-6

Synonyms: C16-H32-O4.Pb, hexanoic acid, 2-ethyl-, lead(2+) salt

Lead BIS(2-Ethylexanoate), lead(2+) salt, lead octoate, lead octanoate

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, and in accordance with the ADG Code, this is also classified as a dangerous good.

Uses: This compound is used as a drier for varnishes and lacquers, as well as in high pressure lubricants, lubricants in the extrusion process, as a stabiliser for vinyl polymers and as a corrosion inhibitor for petroleum.

Appearance: The material is a yellow viscous liquid which does not mix with water.

Health Hazards

Swallowed: The compound is moderately discomforting to the gastro-intestinal tract if swallowed in a large quantity.

Eye: The material is moderately discomforting and is capable of causing a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage and ulceration.

Skin: Lead 2-ethylexanoate is moderately discomforting to the skin and is capable of causing skin reactions which may lead to dermatitis.
Solution of material in moisture on the skin, or perspiration, may increase irritant effects.

Inhaled: The vapour is discomforting to the upper respiratory tract and may be harmful if inhaled. (ChemWatch, 2002b)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: General exhaust is adequate under normal operating conditions, however local exhaust ventilation may be required in specific circumstances. If risk of overexposure exists, an approved respirator should be worn. Correct fit is essential to obtain adequate protection. (ChemWatch, 2002b)

2.2.10 **Lead oxide**

CAS: 1314-41-6

Synonyms: O4-Pb3, Pb3O4, minium, red lead, dilead(II)lead(IV) oxide, lead orthoplumbate, Lead Tetroxide red-lead, lead oxide, red, lead tetraoxide, plumboplumbic oxide, trilead tetroxide, C.I. 77578, C.I. Pigment Red 105, Gold Satinobre, Mineral Orange, Mineral Red, Minium Non-Setting RL-95, Orange Lead, Paris Red, Red Lead Oxide, Sandix, Saturn Red, Bisley Red Lead Oxide, O4Pb3, dileadIIleadIV oxide, lead oxide red, CI 77578, CI Pigment Red 105, Minium NonSetting RL95

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, but in accordance with the ADG code it is classified as a non-dangerous good.

Uses: Lead Oxide has a variety of purposes including use in; storage batteries, glass, pottery and enameling, varnish, purification of alcohol, plaster and ointments. It is also used as a flux for porcelain painting, a protective coating for iron and steel, a coulourant for rubber, an oil-colour for ship paints, a cement for glass, packing for gas and steam pipe joints, pencils for writing on glass, and is utilized in the manufacture of lead peroxide matches.

Appearance: The compound is a bright-red heavy powder that does not mix with water or alcohol. It is soluble in excess glacial acetic acid or hot hydrochloric acid (with evolution of chlorine), as well as in dilute nitric acid with H2O2.

Health Hazards

While the material is moderately discomforting and toxic if swallowed in small amounts, it may be fatal if swallowed in large quantities. Ingestion may also result in nausea, abdominal irritation, pain and vomiting.

Eye: The dust from the compound may be discomforting and abrasive to the eyes, as well as being harmful following absorption. It is capable of causing a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage and ulceration.

Skin: The dust is slowly absorbed by the skin and may cause discomfort. As such, bare unprotected skin should not be exposed to this material (ChemWatch, 2004b). The study by Bress and Bidanset, 1991 indicates that there is no detectable absorption of lead oxide through the guinea pig skin.

Inhaled: The dust could be discomforting to the upper respiratory tract and may be harmful if inhaled. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. (ChemWatch, 2004b)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: Lead Oxide should be used in a well ventilated area. Local exhaust ventilation is required where solids are handled as powders or crystals, as even when particulates are relatively large, a certain proportion will be powdered by mutual friction. If an adverse concentration of the substance occurs in spite of local exhaust, respiratory protection should be considered. (ChemWatch, 2004b)

2.2.11 **Lead nitrate**

CAS: 10099-74-8

Synonyms: Pb(NO3)2, N2-O6-Pb, lead dinitrate, lead(2+) nitrate, lead(II) nitrate, nitric acid, lead(2+) salt, PbNO32, N2O6Pb, lead2 nitrate, leadII nitrate, nitric acid lead2 salt

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, and in accordance with the ADG Code, this is also classified as a dangerous good.

Uses: Lead Nitrate is used as a reagent in analytical chemistry, as a mordant in dyeing and printing of textiles, as a sensitiser in photography as well as being utilized in the manufacture of matches and special explosives.

Appearance: The material is white, almost odourless and crystalline. It mixes with water to form a slightly acidic solution.

Health Hazards

Swallowed: The material is moderately discomforting to the gastro-intestinal tract and may be harmful if swallowed. The substance and/or its metabolites may bind to haemoglobin, with the effect of inhibiting the normal uptake of oxygen. This condition, known as "methaemoglobinemia", is a form of oxygen starvation (anoxia). Symptoms of this condition include cyanosis (a bluish discolouration skin and mucous membranes) and breathing difficulties. Symptoms may not be evident until several hours after exposure. At about 15% concentration of blood methaemoglobin there is an observable cyanosis of the lips, nose and earlobes. Symptoms may be absent though euphoria, flushed face and headache are commonly experienced. At 25-40%, cyanosis is evident but little disability results other than that produced on physical exertion. At 40-60%, symptoms include weakness, dizziness, lightheadedness, increasingly severe headache, ataxia, rapid shallow respiration, drowsiness, nausea, vomiting, confusion, lethargy and stupor. Above 60% symptoms include dyspnea, respiratory depression, tachycardia or bradycardia, and convulsions. Levels exceeding 70% may be fatal.

Eye: The compound is moderately discomforting to the eyes and is capable of causing a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage and ulceration.

Skin: Prolonged exposure of this substance may cause a reaction to the skin (ChemWatch, 2002c). The presence of lead nitrate on the skin can result in rapid absorption of lead and its transport around the body in the plasma. The absorbed lead will then be detectable in sweat and saliva and the rate of absorption elevates with the increase of sweating (Lilley *et al*, 1988). According to Lilley *et al*, 1988 and Stauber *et al*, 1994, there is only a small amount of the absorbed lead in the blood. It is suggested by Lilley *et al*, 1988 that the absorbed lead is quickly transported in plasma and concentrated in extracellular fluid pool (sweat and saliva).

Inhaled: The dust from this compound may be discomforting to the upper respiratory tract. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. Repeated exposure to high concentrations may cause permanent damage. (ChemWatch, 2002c)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: Under normal operating conditions, general exhaust is adequate under. Local exhaust ventilation may be required in specific circumstances. If risk of overexposure exists, approved respirator should be worn. (ChemWatch, 2002c)

2.2.12 **Lead naphthenate**

CAS: 61790-14-5

Synonyms: lead naphthanate, naphthenic acid, lead salt, cyclohexanecarboxylic acid, lead salt, naphthenic acid lead salt, cyclohexan acid lead salt, cyclohexanecarboxyli acid lead salt

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, but in accordance with the ADG code it is classified as a non-dangerous good.

Uses: Lead Naphthenate is used as a dryer in paints, and as an additive in lubricating oils.

Appearance: the compound is brown and semi-solid. It does not mix with water and has an unpleasant odour.

Health Hazards

Swallowed: The material may be mildly discomforting to the gastro-intestinal tract and can cause further damage if swallowed in large quantities.

Eye: The material is moderately discomforting to the eyes and is capable of causing a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage and ulceration.

Skin: The material is moderately discomforting to the skin and is capable of causing a skin reaction which may lead to dermatitis (ChemWatch, 2004c). According to Lilley *et al*, 1988, there is an assumption that the absorption of lead through the skin is only possible if lead is present as organolead compounds such as naphthanates. However, according to Sun *et al* 2002 and Stauber *et al*, 1994: “significant amounts of inorganic lead compounds can be absorbed through the skin.” ATSDR (2005) reports the following: In a comparative study of dermal absorption of inorganic and organic salts of lead conducted in rats, approximately 100 mg of lead was applied in an occluded patch to the shaved backs of rats. Based on urinary lead measurements made prior to and for 12 days following exposure, lead compounds could be ranked according to the relative

amounts absorbed (i.e., percent of dose recovered in urine; calculated by ATSDR): lead naphthalene (0.17%), lead nitrate (0.03%), lead stearate (0.006%), lead sulfate (0.006%), lead oxide (0.005%), and metal lead powder (0.002%). This rank order (i.e., lead naphthalene>lead oxide) is consistent with a rank ordering of penetration rates of inorganic and organic lead salts through excised skin from humans and guinea pigs: lead nuolate (lead linoleic and oleic acid complex) > lead naphthanate > lead acetate > lead oxide (nondetectable) (Bress and Bidanset 1991).

Inhaled: While this is considered an unlikely cause of exposure in the industrial environment, Lead fumes are toxic and act as a cumulative poison. Regular blood testing should be considered for workers who are regularly exposed. (ChemWatch, 2003c)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: General exhaust is adequate under normal operating conditions. If risk of overexposure exists, workers should wear an approved respirator. (ChemWatch, 2003c)

2.2.13 **Lead peroxide**

CAS: 1309-60-0

Synonyms: Pb-O2, lead brown, lead oxide brown, lead dioxide, lead superoxide, PbO2

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, and in accordance with the ADG Code, this is also classified as a dangerous good.

Uses: Lead Peroxide is used as an oxidizing agent, in electrodes, in lead-acid storage batteries, as a curing agent for polysulphide elastomers, in textiles, in matches, in explosives and as an analytical reagent.

Appearance: The compound is dark brown and in the form of hexagonal crystals. It is insoluble in water and alcohol but Soluble in glacial acetic acid. When heated it evolves into oxygen, first forming Pb3O4. It is also odourless.

Health Hazards

Swallowed: The material is moderately discomforting to the gastro-intestinal tract and may be harmful if swallowed. Gastric acids solubilise lead and its salts and lead absorption occurs in the small bowel. Particles of less than 1 micron diameter are substantially absorbed by the alveoli following inhalation. The Lead is then distributed to the red blood cells and has a half-life of 35 days. It is subsequently either redistributed to soft tissue & bone-stores, or eliminated. The kidney accounts for 75% of daily lead loss; integumentary and alimentary losses account for the remainder.

Neurasthenic symptoms are the most common symptoms of intoxication. Lead toxicity produces a classic motor neuropathy but acute encephalopathy appears infrequently in adults. Obvious clinical symptoms occur in adults when whole-blood lead exceeds 80 ug/dL.

Eye: The dust may produce eye discomfort causing smarting, pain and redness.

Skin: The compound is moderately discomforting to the skin.
Open cuts, abraded or irritated skin should not be exposed to this material.

Inhaled: The dust is highly discomforting to the upper respiratory tract is inhaled. (ChemWatch, 2005c)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: Local exhaust ventilation is required when solids are handled as powders or crystals, even when particulates are relatively large, as a certain proportion will be powdered by mutual friction. Exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace.
If an adverse concentration occurs in spite of local exhaust, respiratory protection should be considered. (ChemWatch, 2005c)

2.2.14 **Lead carbonate (white lead)**

CAS: 1319-46-6

Synonyms: 2PbCO3.Pb(OH)2, white lead, basic carbonate white lead, Basic lead carbonate, lead carbonate hydroxide, lead bis (carbonato(2))dihydroxytri-bis(carbonato)dihydroxytrilead, C.I. Pigment White 1, C.I. 77597, lead subcarbonate, ceruse, Lead flake, C2-H2-O8-Pb3

Uses: Lead carbonate is used as a white pigment in paints and ceramic glazes.

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, and in accordance with the ADG Code, this is also classified as a dangerous good.

Appearance: The compound is a white, heavy powder that is insoluble in water and alcohol, but soluble in acetic acid and dilute nitric acid.

Health Hazards

Swallowed: The material is moderately discomforting to the gastro-intestinal tract and may be harmful if swallowed.

Eye: The material is moderately discomforting to the eyes and is capable of causing a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage and ulceration.

Skin: The compound is moderately discomforting to the skin. Open cuts, abraded or irritated skin should not be exposed to this material. Toxic effects may result from skin absorption.

Inhaled: Lead carbonate is moderately discomforting to the upper respiratory tract and may be harmful if inhaled. (ChemWatch, 2002d)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in specific circumstances. If risk of overexposure exists, workers should wear an approved respirator. Correct fit is essential to obtain adequate protection. (ChemWatch, 2002d)

2.2.15 **Lead chrome 1244**

CAS: Unknown

Synonyms: Light Chrome. We don't have an MSDS on lead chrome 1244 so all the following information comes from the ChemWatch MSDS for Ameron 535 Industrial Enamel Light Chrome [66797]. This product is a mixture of lead chrome and xylene among other things.

Hazardous Nature: According to the Criteria of NOHSC, this is a hazardous substance, and in accordance with the ADG Code, this is also classified as a dangerous good.

Uses: Lead Chrome is used as an industrial air drying, spraying, gloss enamel. Application is usually by spray atomisation in a ventilated spray booth, after thinner is used for a viscosity reduction. It is used for industrial purposes only and contains lead pigments as indicated on the label. It is specifically NOT to be used on toys, furniture, buildings, or on, in or around the home or where contact with food or drinking water may occur (ChemWatch, 2004c). However, according to SUSDP No. 20 all lead compounds are restricted in the same way.

Appearance: Lead chrome is a yellow, highly flammable liquid. It does not mix with water and has a strong solvent smell. It does mix with enamel thinners and aromatic solvents.

Health Hazards

Swallowed: The liquid is highly discomforting and may be toxic if swallowed. Ingestion could result in nausea, pain, vomiting. Vomit entering the lungs by aspiration may also cause potentially lethal chemical pneumonitis.

Eye: The liquid could produce eye discomfort and is capable of causing temporary impairment of vision and/or transient eye inflammation, and ulceration. The vapour is mildly discomforting to the eyes.

Skin: The liquid is discomforting to the skin if exposure is prolonged and has the capacity to cause skin reactions which may lead to dermatitis. Open cuts, abraded or irritated skin should not be exposed to this material. The compound may also accentuate any pre-existing dermatitis condition.

Inhaled: The vapour is highly discomforting to the upper respiratory tract. The hazard is increased at higher temperatures. Xylene is a central nervous system depressant. Inhalation of high concentrations of gas/vapour causes lung irritation with coughing and nausea, central nervous depression with headache and dizziness, slowing of reflexes,

fatigue and inco-ordination. If exposure to highly concentrated solvent atmosphere is prolonged this may lead to narcosis, unconsciousness, even coma and possible death. (ChemWatch, 2004c)

Chronic Health Effects: Same as the chronic health effects caused by lead exposure outlined in Section 2.1.

Engineering Controls: This compound should be used in a well-ventilated area. Spraying must be carried out in conditions conforming to local state regulations. Unprotected personnel must vacate the spraying area. While general exhaust is adequate under normal operating conditions, local exhaust ventilation may be required in specific circumstances. (ChemWatch, 2004c)

2.2.16 **Lead acetate**

CAS: 301-04-2

Synonyms: Lead Acetate, Trihydrate; lead (II) acetate, trihydrate; acetic acid lead (II) salt, trihydrate; lead diacetate, trihydrate; Salt of Saturn

Hazardous Nature: According to the Criteria of NOHSC, this is a …… substance, and in accordance with the ADG Code, it is also classified as a …. Good.

Uses: This material is used in the production of ‘progressive hair dyes’.

Appearance: Lead acetate is found in white chystalline granuales. It has a slight acetic acid odour, and is soluble in water.

Health Hazards

Swallowed: If ingested this material can cause abdominal pain and spasms, nausea, vomiting and headaches. Acute poisoning can lead to muscle weakness, "lead line" on the gums, metallic taste, definite loss of appetite, insomnia, dizziness, high lead levels in blood and urine, and in extreme cases, coma and death (Mallincrodt Baker Inc., 2005).

Eye: While absorption can occur through eye tissue, more common hazards are local irritation and abrasion (Mallincrodt Baker Inc., 2005).

Skin: Following skin application of ^{203}Pb-labeled lead acetate in cosmetic preparations (0.12 mg Pb in 0.1 mL or 0.18 mg Pb 0.1 g of a cream) to eight male volunteers for 12 hours, absorption was ≤0.3%, based on whole-body, urine and blood ^{203}Pb measurements, and was predicted to be 0.06% during normal use of such preparations (Moore et al. 1980). Most of the absorption took place within 12 hours of exposure (ATSDR, 2005). Also see the comment regarding skin absorption of lead acetate in Section 2.2.12.

Inhaled: Lead acetate can be absorbed through the respiratory system. Local irritation of bronchia and lungs can occur and, in cases of acute exposure, symptoms such as metallic taste, chest and abdominal pain, and increased lead blood levels may follow (Mallincrodt Baker Inc., 2005).

Chronic Health Effects: Lead is a cumulative poison and exposure even to small amounts can raise the body's content to toxic levels. The symptoms of chronic exposure are like those of ingestion poisoning; restlessness, irritability, visual disturbances, hypertension and gray facial color may also be noted (Mallincrodt Baker Inc., 2005).

Engineering Controls: A system of local and/or general exhaust is recommended to keep exposures below airborne limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area (Mallincrodt Baker Inc., 2005).

2.2.17 **Lead sulfide**

CAS: 1314-87-0

Synonyms: lead sulphide, plumbous sulfide, plumbous sulphide, galena, lead (II) sulphide, lead (II) sulfide, Natural lead sulfide

Hazardous Nature: According to the Criteria of NOHSC, this is a xxx? substance, and in accordance with the ADG Code, it is also classified as…..xxx

Uses: This material is used in ceramic glazes, infrared radiation dectectors and semicondictors (New Jersey Department of Health and Senior Services, 2005).

Appearance: Lead Sulfide exists as either black powder or silvery metallic crystals. It is an odourless substance that does not mix with oxidizing agents, acids or water.

Health Hazards

Swallowed: This compound is harmful when ingested orally. It can cause gastrointestinal irritation with nausea, vomiting and diarrhea. As with other lead compounds, it may cause toxic effects in the blood-forming organs, kidneys, and central nervous

Eye: Lead Sulfide causes eye irritation, and may cause visual disturbance.

Skin: It may cause skin irritation

Inhaled: This compound is harmful when inhaled. It may cause symptoms similar to those experienced when swallowed.

Chronic Health Effects: Chronic exposure to Lead Sulfide may result in plumbism which is characterized by lead line in gum, headache, muscle weakness, and a change in mental wellbeing.

Engineering Controls: Adequate ventilation.

2.2.18 Lead acetate trihydrate

CAS: 6080-56-4

Synonyms: Acetic Acid, Lead (II) Salt, Lead (II) Acetate

Hazardous Nature: According to the Criteria of NOHSC, this is a xxx substance, and in accordance with the ADG Code, it is also classified as…..xxx

Uses: xxx?

Appearance: The compound exists as either a clear, colourless liquid or in the form of white crystals.

Health Hazards

Swallowed: Ingestion of Lead Acetate Trihydrate poses no real toxic effect in small amounts, but repeated (chronic) ingestion can cause serious problems subsequent to lead poisoning. Ingestion may cause nausea (Ricca Chemical Company, 2001).

Eye: This compound may be mildly discomforting to the eyes if contact occurs, causing redness and tearing.

Skin: If contacted with the skin, Lead Acetate Trihydrate may be irritating. According the Ricca Chemical Company, acute poisoning is rare for any route of exposure (2001).

Inhaled: This compound is harmful when inhaled. Symptoms may include headache, insomnia, persistent vomiting, blurred vision, irritability, anemia, hypertension, anxiety,

and the appearance of a dark line along the gums in the mouth (Ricca Chemical Company, 2001).

Chronic Health Effects: xxx

Engineering Controls: No specific controls are needed. Normal room ventilation is adequate (Ricca Chemical Company, 2001).

2.2.19 Lead chloride

CAS: 7758-95-4 100

Synonyms: Lead (II) Chloride

Hazardous Nature: According to the Criteria of NOHSC, this is a xxx? substance, and in accordance with the ADG Code, it is also classified as…..xxx

Uses: Was used as a cosmetic product in ancient Egypt (see Section 2.5.7). Modern day uses are unknown.

Appearance: Lead Chloride is found in the form of solid grey crystals.

Health Hazards

Swallowed: This substance is hazardous if ingested

Eye: There are no acute health effects arising from contact of this material with the eyes.

Skin: xxx

Inhaled: This substance is hazardous if inhaled.

Chronic Health Effects: Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

Engineering Controls: Recommended control methods include the use of process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, it is nessacary to use ventilation to keep exposure to airborne contaminants below the exposure limit (EMD Chemicals Inc., 2003).

SECTION TWO REFERENCES

- ATSDR (Agency for Toxic Substances and Disease Registry) (2005). DRAFT Toxicological Profile for Lead. US Department of Health & Human Services, Public Health Service, Atlanta, GA <http://www.atsdr.cdc.gov/toxprofiles/tp13.pdf> Accessed 2006 Feb 21.
- Aufderheider AC, Wittmers LE. (1992) Selected aspects of the spatial distribution of lead in bone. *Neurotoxicology* **13**: 809-820.
- Berlin K, Gerhardsson L, Borjesson J, et al. (1995) Lead intoxication caused by skeletal disease. *Scand J Work, Environ Health* **21**: 296-300.
- Bress, W.C., and Bidanset, J.H. (1991). Percutaneous in vivo and in vitro absorption of lead. Vet Hum Toxicol. 1991 Jun;33(3):212-4. <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=1858297&dopt=Abstract>. Accessed 2006 Feb 21.
- Chemwatch (2001a) Material Safety Data Sheet for C.I. Pigment Red 104-Molybdate Orange [16976]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2001b) Material Safety Data Sheet for Lead Chromate Oxide [39418]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.

- Chemwatch (2002a) Material Safety Data Sheet for Lead Sulphate [22565]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2002b) Material Safety Data Sheet for Lead Bis(2-Ethylexanoate) [4037-11]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2002c) Material Safety Data Sheet for Lead Nitrate [1469]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2002d) Material Safety Data Sheet for Lead Carbonate Hydroxide [63540]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2003a) Material Safety Data Sheet for Lead Sulphocromate [12960]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2003b) Material Safety Data Sheet for Lead Molybdate [22611]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2003c) Material Safety Data Sheet for Lead Naphthenate [41628]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2004a) Material Safety Data Sheet for Lead Octoate [4076-80]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2004b) Material Safety Data Sheet for Lead Tetroxide - Red Lead [25611]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2004c) Material Safety Data Sheet for Ameron 535 Industrial Enamel Light Chrome [66797]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.

- Chemwatch (2005a) Material Safety Data Sheet for Lead Monoxide [10689]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2005b) Material Safety Data Sheet for Lead Chromate [22612]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Chemwatch (2005c) Material Safety Data Sheet for Lead Dioxide [1872]. Available for purchase from <http://www.chemsw.com/10250.htm>. Accessed 2005 Nov 14.
- Cheng Y, Willett WC, Schwartz J, *et al*. (1998) Relation of nutrition to bone lead and blood lead levels in middle-aged to elderly men. The Normative Aging Study. *Am J Epidemiol* **147**: 1162-74.
- Division of Occupational Safety, Department of Labor, Commonwealth of Massachussets (1998). Why is the Reduction of Lead from Our Environment so Important? Health Hazards of Lead for Workers and Children. <http://www.mass.gov/dos/leaddocs/lead_hlthhaz.htm>. Accessed: 2006 Feb 14.
- Elmarsafawy SF, Tsaih SW, Korrick S, *et al*. (2002) Occupational determinants of bone and blood lead levels in middle aged and elderly men from the general community: the Normative Aging Study. *Am J Ind Med* **42**: 38-49.
- EMD Chemicals Inc. 2003 Material Safety Data Sheet - Lead Chloride, Gibbston, NJ, United States <http://www.vwrsp.com/msds/10/EM-/EM-LX0140-1.pdf> Accessed 2006 Mar 7.
- EMD Chemicals Inc. 2004 Material Safety Data Sheet - Lead Chromate, Gibbston, NJ, United States <http://www.vwrsp.com/msds/10/EM-/EM-LX0145-1.pdf> Accessed 2006 Mar 7.
- Federal Register of Legislative Instruments (2004) Industrial Chemicals (Notification and Assessment) Act 1990, No. 231, AGO, Canberra
- Fischbein, A (1998). Occupational and environmental exposure to lead. In: Environmental and Occupational Medicine, Rom, WN (Ed), Philadelphia, Lippincott-Raven Publishers, p. 973.

- Fisher Scientific 2005 Material Safety Data Sheet- Lead Sulfide <https://fscimage.fishersci.com/msds/12750.htm> Accessed 2006 Mar 7.
- Gavaghan H (2002). Lead unsafe at any level. Bulletin of World Health Organisation, 80(1):82 http://whqlibdoc.who.int/bulletin/2002/Vol80-No1/bulletin_2002_80(1)_82-82.pdf Accessed 2006 Mar 1.
- Hernberg S (2000) Lead poisoning in a historical perspective. Am J Industrial Medicine, 38:244-254.
- Hu H, Wu MT, Cheng Y, *et al*. (2001) The delta-aminolevulinic acid dehydratase (ALAD) polymorphism and bone and blood lead levels in community-exposed men: the Normative Aging Study. *Environ Health Perspect* **109**: 827-32.
- Korrick SA, Schwartz J, Tsaih SW, *et al*. (2002) Correlates of bone and blood lead levels among middle-aged and elderly women. *Am J Epidemiol* **156**: 335-43.
- LEAD Group, The (2005) Countries possibly still to ban leaded petrol as at 20th Oct 2005 <http://www.lead.org.au/fs/fst27.html> Accessed 2005 Dec 28.
- Lilley, S. G., Florence, T. M., and Stauber, J. L , CSIRO Division of Fuel Technology, NSW, Australia (1988) The use of sweat to monitor lead absorption through the skin. Science of the Total Environment 1988 Oct 15;76(2-3):267-78. <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=3238426&dopt=Abstract> Accessed 2006 Feb 21.
- Lin C, Rokho K, Tsaih S, et al.(2004) Determinants of bone and blood lead levels among minorities living in the Boston area.) *Environ Health Perspect* **112**: 1147-1151.
- Mahaffey KR, Annest JL,Roberts *et al*. (1982) National estimates of blood lead levels: United States 1976-1980: association with selected demographic and socioeconomic factors. *New Engl J Med* **307**: 573-579
- Mallincrodt Baker Inc. (2005) Material Safety Data Sheet- Lead Acetate <http://www.jtbaker.com/msds/englishhtml/l2434.htm> Accessed 2006 Mar 7.
- Mallincrodt Baker Inc. 2005 Material Safety Data Sheet- Lead Acetate at: <http://www.jtbaker.com/msds/englishhtml/l2434.htm> Accessed 2006 Mar 7.
- Moore MR, Meredith PA, Watson WS, et al. 1980. The percutaneous absorption of lead-203 in humans from cosmetic preparations containing lead acetate, as

assessed by whole-body counting and other techniques. Food Cosmet Toxicol 18:399-405.

- Muntner P, Menke A, DeSalvo KB, *et al* . (2005) Continued decline in blood lead levels among adults in the United States: the National Health and Nutrition Examination Surveys. *Arch Int Med* **165**: 2155-61.
- New Jersey Department of Health and Senior Services, 2005 <http://www.state.nj.us/health/eoh/rtkweb/1113.pdf> Accessed 2006 Mar 7.
- New Jersey Department of Health and Senior Services, 2005 <http://www.state.nj.us/health/eoh/rtkweb/1113.pdf> Accessed 2006 Mar 7.
- New Jersey Department of Health and Senior Services, 2005 <http://www.state.nj.us/health/eoh/rtkweb/1113.pdf> Accessed 2006 Mar 7.
- NHANES [xxx – add NHANES reference referred to in Chronic Health Effects section 2.1 above]
- NICNAS (2005) Australian Inventory of Chemical Substances (AICS) Last modified 30th November 2005 <http://www.nicnas.gov.au/Industry/AICS.asp>. Accessed 2006 Feb 27.
- NICNAS (2005a) National Industrial Chemicals Notification and Assessment Scheme: The Australian Government Regulator of Industrial Chemicals <http://www.nicnas.gov.au/>. Accessed 2005 Nov 12.
- NICNAS (2005c) CONSULTANCY CONTRACT between The COMMONWEALTH OF AUSTRALIA as represented by the National Industrial Chemicals Notification and Assessment Scheme in the Department of Health and Ageing and THE LEAD EDUCATION ABATEMENT DESIGN (LEAD) GROUP in relation to Services for A Consultancy to Provide a Hazard Assessment Report for Lead Compounds Used in Surface Coatings and Inks and Cosmetics and Toiletries and Current Controls for Reducing Exposure to Lead Compounds Used in Surface Coatings and Inks and Cosmetics and Toiletries, 9th September 2005, Sydney.
- NICNAS (National Industrial Chemicals Notification and Assessment Scheme) (2000) FULL PUBLIC REPORT Glasurit High Solid 2K Commercial Vehicle Topcoat, June 2002

<http://www.nicnas.gov.au/publications/CAR/new/PLC/PLC0100FR/plc129fr.pdf>. Accessed 2005 Dec 28.

- NIOSH, 2004, International Chemical Safety Cards, <http://www.cdc.gov/niosh/ipcsneng/neng0003.html> Accessed 2006 Mar 7.
- Nordberg M, Winblad B, Fratiglion L, *et al*. (2000) Lead Concentrations in Elderly Urban People Related to Blood Pressure and Mental Performance: Results From a Population-Based Study. *Am J Ind Med* **38**:290-294.
- NSW Public Health Bulletin November –December 1997.
- Physical & Theoretical Chemistry Lab (PTCL) Material Safety Data Sheet- Lead Sulfide 2004 Oxford University, England, <http://ptcl.chem.ox.ac.uk/MSDS/LE/lead_sulfide.html> Accessed 2006 Mar 7.
- Ricca Chemical Company 2001 Material Safety Data Sheet - Lead Acetate Trihydrate, Texas, United States <www.riccachemical.com/techsupp/msds.aspx?qs=4293.4> Accessed 2006 Mar 7.
- Saltzman BE, Gross SB, Yeager DW, *et al.* (1990) Total body burdens and tissue concentrations of lead, cadmium, copper, zinc, and ash in 55 human cadavers. *Environ Research* **52**:126-45.
- Schwartz BS, Stewart WF, Bolla KI *et al*. (2000) Past adult exposure is associated with longitudinal decline in cognitive function. *Neurology* **55** 1144-1150
- Siddiqui MK, Srivastava S, Mehrotra PK. (2002) Environmental exposure to lead as a risk for prostate cancer. *Biomed Environ Sc* **15**:298-305.
- Silbergeld E (1997) Preventing lead poisoning in children .Annu Rev Public Health, 18:187-210.
- Standards Australia (1995) Guide to Lead Paint Management; Part 1: Industrial Applications AS no. 4361.1. Available for purchase from <http://www.saiglobal.com/shop> Accessed 2006 Feb 18.
- Stauber, J.L., Florence, T.M, Gulson, B.L, and Dale, L.S. (1994). Percutaneous absorption of inorganic lead compounds. Sci Total Environ. 1994 May 2;145(1-2):55-70.

<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=8016629&query_hl=5&itool=pubmed_docsum>. Accessed 2006 Feb 21.

- Sun, C.C., Wong, T.T., Hwang, Y.H., Chao, K.Y., Jee, S.H., and Wang, J.D., Department of Dermatology, National Taiwan University Hospital, Taipei, Taiwan. (2002). Percutaneous absorption of inorganic lead compounds. AIHA J (Fairfax, Va). 2002 Sep-Oct;63(5):641-6. <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12529920>. Accessed 2006 Feb 21.
- Tsaih SW, Korrick S, Schwartz J, *et al*. (2004) Lead, diabetes, hypertension, and renal function: the normative aging study. *Environ Health Perspect* **112**: 1178-82.
- Weisskopf MG, Wright RO, Schwartz J, *et al*. (2004) Cumulative lead exposure and prospective change in cognition among elderly men: the VA Normative Aging Study. *Am Jf Epidemiol* **160**:1184-93.
- Zaluzny, Stephen (2005) *Personal communication – comments on the first draft of the current report to NICNAS,* 2005 Dec 20.

List of National and International Reports [which are yet to be checked out to see if they are useful either for the Hazard Assessment or the Controls sections] [xxx – research required – to check out the following documents and decide what if anything should be added from them to the report and where it should be added]

- Comlaw (1991) Occupational Health and Safety (Commonwealth Employment) Act. "An Act to promote the occupational health and safety of persons employed by the Commonwealth and Commonwealth authorities, and for related purposes" (Comlaw, 1991). (Australia) <http://www.comlaw.gov.au/ComLaw/Management.nsf/current/bytitle/AB1F2638013E34EFCA256F710006F863?OpenDocument&mostrecent=1> Accessed 2005 Nov 18.
- NPI (National Pollutant Inventory) (1999) Emission Estimation Technique Manual for Surface Coating

<http://www.npi.gov.au/handbooks/approved_handbooks/pubs/fsurfc.pdf>. Accessed 2005 Aug 25.

- OECD Organization for Economic Cooperation and Development (1993) Risk Reduction Monograph no.1: Lead, Background and National Experience with Reducing Risk
- Standards Australia (2004) Risk Management AS/NZS 4360. Available for purchase from <http://www.saiglobal.com/shop> Accessed 2006 Feb 18th.
- WHO IPCS Environmental Health Criteria 165: Inorganic Lead <http://www.inchem.org/documents/ehc/ehc/ehc165.htm> Accessed 2005 Aug 25th.

[xxx – research required – to check out the following documents and decide what if anything should be added from them to the report and where it should be added]

- US ATSDR Agency for Toxic Substances and Disease Registry (1999) Toxicological Profile for Lead <http://www.atsdr.cdc.gov/toxprofiles/tp13.pdf> Accessed 2005 Aug 25.
- US ATSDR Agency for Toxic Substances and Disease Registry (2005) Lead Toxicity <http://www.atsdr.cdc.gov/HEC/CSEM/lead/whosat_risk.html> Accessed 2005 Aug 25.

3. REGULATIONS CONTROLLING EXPOSURE TO LEADED SURFACE COATINGS AND INKS

3.1 **Introduction**

There follows a review of regulatory and voluntary industry controls in Australia and overseas focusing on the following categories:

- Manufacturing / Importation:

regulations put in place to determine the amount of lead legally allowed in the various products.

occupational health and safety measures put in place to protect Australian workers from exposure to lead compounds. This will include such measures as protective gear and air circulation.

- Transportation:

how lead compounds are transported to the factory, and how the products containing lead are then transported from the factory including the Federal Office of Road Safety, *Australian Code for the Transport of Dangerous Goods by Road and Rail*, 6th Edition as well as information and controls from the United Nations Committee of Experts on the Transport of Dangerous Goods.

- Using / Handling:

controls currently in place for people using lead-based surface coatings and inks, including a comparison between regulations for industrial uses and those for public uses

issues of maintenance and application, particularly in regard to lead-based paints.

- Storing:

regulations put in place in regard to labeling products containing lead, including an examination of the regulations relating to containers used to store these products and warning labels required.

- Disposal / Removal:

regulations and/or warnings currently in place to ensure the safe disposal and/or removal of surface coatings containing lead.

[xxx – Research required to determine as we go along that the Regulatory Controls and Voluntary Industry Controls on Lead in Surface Coatings and Inks sections fulfill the promise of this overview of them]

3.2 **Regulatory Controls in Australia**

In Australia it is the role of the Commonwealth and State and Territory Governments to implement legislation that addresses the control of risks in the workplace. Each state and Territory has a principle Occupational Health and Safety (OHS) Act which sets out certain requirements for the workplace. Some hazards, such as the use of inorganic lead, have the potential to cause much injury, so specific regulations or codes of practice are warranted to address these risks. The following documents all relate to national legislation and codes of practice. It is important to remember, however, that these national regulations do not become legally enforceable until they are adopted by the State and Territory governments.

3.2.1 **National Standard for the Control of Inorganic Lead at Work**

Reference: National Standard for the control of Inorganic Lead at work [NOHSC:1012(1994)] National Occupational Health and Safety Commission, Canberra, AusInfo.

Organization: The National Occupational Health and Safety Commission (NOHSC) (1994a). NOHSC creates national standards which are only made mandatory through implementation by States and Territories. The NOHSC was abolished on 15th November 2005 and its functions transferred to the Australian Safety and Compensation Council (ASCC).

Importance of Article: This document is extremely important in understanding the regulatory controls in place in the Australian workplace to counteract the potential hazard of inorganic lead. It goes into a lot of detail about specific safety precautions that can be taken to avoid the hazards involved in the use of lead at work.

Key Points and Important Information:

- The document asserts that Australia is the largest mine producer of lead in the Western world and is also the largest exporter, with the Australian lead industry accounting for about one quarter of the world's exports (NOHSC, 1994a, p7). These figures highlight the importance of implementing regulatory controls to minimize the risk of lead-exposure to employees in the workplace.

- The major routes of entry of inorganic lead into the body during cases of occupational exposure are through inhalation and ingestion of dust and fumes during various manufacturing and production processes (NOHSC, 1994a, p7).

- According to NOHSC, a ‘lead risk job’ is one in which the blood level of the employee could be expected to rise above 1.45 µmol/L (30 µg/dL) (NOHSC, 1994a, p21).

- Certain safety procedures outlined in the standard include the following:
    - Employers must provide applicants of jobs where lead is used with information concerning the health risks and toxic effects associated with exposure.
    - Material Safety Data Sheets (MSDS) must be received from the supplier on the first delivery of lead-containing hazardous substances, and they must be readily available for the employee to view.
    - All hazardous products containing lead at work should be properly labelled, and these labels should not be defaced, modified or altered in any way (NOHSC, 1994a, p19)

- The employer must also ensure that a register of all lead-containing hazardous products is kept and that this register is available to all employees in danger of lead-exposure.
- The employer must provide the employee with an induction before starting work, and at least annually after that. In such sessions, information should be given concerning the health hazards involved in the use of hazardous materials containing lead, as well as the correct use of protective equipment.
- The employer should ensure that "suitable and sufficient" assessment is made as to the extent of the risks to health present in the workplace where there exists a potential for lead exposure (NOHSC, 1994a, p20).
- All engineering controls, safe work practice and protective equipment in the workplace should be adequately maintained (NOHSC, 1994a, p21)
- Where possible the employer should make sure that the level of lead in the air likely to be inhaled by employees does not exceed the exposure standard (0.15mg/m3 at the time of printing). When this is not practical, the employer must provide the worker with suitable respiratory protective equipment, and place appropriate warning signs in the lead process area (NOHSC, 1994a, p22).
- Employers should ensure that contamination of areas outside the lead process area is avoided, and that employees do not "eat, drink, chew gum, smoke or carry smoking materials in any lead process area" (NOHSC, 1994a, p22). They should also provide a room away from the lead contaminated for eating and drinking, and employees must wash and remove any protective clothing before entering.
- People can be excluded from lead-risk jobs due to: personal medical conditions, pregnancy and breast feeding (NOHSC, 1994a, p24).
- The employers should provide health surveillance for employees working in lead-risk jobs. This should be provided by a suitable authorized medical practitioner, at no extra cost to the employee. The results of these health surveillances should be maintained for 10 years after the date of the last entry (NOHSC, 1994a, p25).

Biological Monitoring

- Biological monitoring is an important part of this surveillance process, and "consists of the measurement of lead in whole blood or packed red cells, sampled as capillary or venous blood as appropriate, and related measurements as required"(NOHSC, 1994a, p26). Results of this biological monitoring should be given to the employee as soon as possible after the testing is complete.
- If the results of the biological monitoring confirm that the employee has a blood lead level that is at or above:

  2.41 µmol/L (50 µg/dL) - for males and females not of reproductive capacity,

  2.41 µmol/L (50 µg/dL) - for males of reproductive capacity,

  0.97 µmol/L (20 µg/dL) - for females of reproductive capacity,

  0.72 µmol/L (15 µg/dL) - for females who are pregnant or breast feeding,

  (NOHSC, 1994a, p27)

  the employer must immediately remove the employee from the lead-risk job and arrange for a medical examination. Similarly if a female employee advices the employer she is pregnant or breast feeding, she should immediately be removed from the lead-risk job.
- An employer should not allow an employee to return to a lead-risk job until the blood lead level is confirmed to be less than:

  1.93 µmol/L (40 µg/dL) - for males and females not of reproductive capacity,

  1.93 µmol/L (40 µg/dL) - for males of reproductive capacity,

  0.48 µmol/L (10 µg/dL) - for females of reproductive capacity, including females who have ceased their pregnancy and are not breast feeding;

  and the employee is certified as fit to return back to work (NOHSC, 1994a, p28).
- If the results of biological monitoring show that the employee's blood lead level is at or above:

  1.93 µmol/L (40 µg/dL) - for males and females not of reproductive capacity,

  1.93 µmol/L (40 µg/dL) - for males of reproductive capacity,

  0.72 µmol/L (15 µg/dL) - for females of reproductive capacity,

  on three consecutive occasions; or at or above:

2.41 µmol/L (50 µg/dL) - for males and females not of reproductive capacity,
2.41 µmol/L (50 µg/dL) - for males of reproductive capacity,
0.97 µmol/L (20 µg/dL) - for females of reproductive capacity,
on a single occasion; an employer shall take action to identify and assess the source of lead exposure and control that lead exposure (NOHSC, 1994a, p29).

3.2.2 National Code of Practice for the Control and Safe Use of Inorganic Lead at Work

Reference: National Code of Practice for the control and Safe Use of Inorganic Lead at work [NOHSC: 1012(1994)] National Occupational Health and Safety Commission, Canberra, AusInfo.

Organization: National Occupational Health and Safety Commission (NOHSC) (1994b)

Importance of Article: This code of Practice provides a practical guide on how to comply with the National Standard for the Control of Inorganic Lead at Work. It doesn't present any new regulations, it just outlines the ones already described in the *National Standard for the control of Inorganic Lead at work.*

Key Points: All the information has already been provided in the national standard.

3.2.3 Approved Code of Practice on the Control and Safe Use of Inorganic Lead in Commonwealth Employment

Reference: Comcare (2004) Approved Code of Practice on the Control and Safe Use of Inorganic Lead in Commonwealth Employment

Organization: Comcare is responsible for workplace safety, rehabilitation and compensation under Commonwealth jurisdiction. Its aim is to reduce the human and financial costs of workplace injuries, and to return injured workers to work.

Importance of Article: Commonwealth employees and others responsible for the use of lead at work are required to follow the guidelines outlined in this document. The Safety, Rehabilitation and Compensation Committee (SRC) decided that they would incorporate the *National Standard for the Control of Inorganic Lead at Work* and the *National Code of Practice for the Control and Safe Use of Inorganic Lead at Work* into this approved code of practice. This document now replaces the former two as the key standard for the control of inorganic lead at work.

Key Points: All the information provided in this document is similar, if not exactly the same, as the information in the *National Standard for the Control of Inorganic Lead at Work.* All the regulations remain the same, as do the blood-lead levels outlined above.

3.2.4 National Occupational Health and Safety Commission Regulatory Package

The following six references from the NOHSC were released together as part of the workplace hazardous substances regulatory package. As the compounds of lead which are being investigated in this project are all classified as 'hazardous substances', these regulations are an important part in understanding the controls placed on industries in Australia.

National Model Regulations for the Control of Workplace Hazardous Substances

Reference: National Model Regulations for the Control of Workplace Hazardous Substances [NOHSC: 1005 (1994)] National Occupational Health and Safety Commission, Canberra, AusInfo.

Organization: National Occupational Health and Safety Commission (NOHSC) (1994c)

Importance of Article: While this is undoubtedly an important document in the development of workplace regulations, it does not deal with lead and its compounds in

any specific way. As the *National Standard for the control of Inorganic Lead at work* is primarily based on the guidelines outlined in this document, but goes into greater detail about the hazards involved in the use of lead, this model is not of particular importance to the current report.

Key Points and Important Information:

- The objective of this document is to "minimise the risk of adverse health effects due to the exposure of hazardous substances in the workplace" (NOHSC, 1994, p5).

- Cosmetic products and toiletries are specifically exempt from these regulations, so this cannot be used for that particular section of the report (NOHSC, 1994, p5).

National Code of Practice for the Control of Workplace Hazardous Substances

Reference: National Code of Practice for the Control of Workplace Hazardous Substances [NOHSC: 2007(1994)] National Occupational Health and Safety Commission, Canberra, AusInfo.

Organization: National Occupational Health and Safety Commission (NOHSC) (1994b)

Importance of Article: This is a useful document as it specifies how hazardous substances should be classified, and what controls should be used to reduce the risk of injury.

Key Points and Important Information:

- This code of practice asserts that manufacturers and importers of substances used at work must determine whether such substances are hazardous by using the *List of Designated Hazardous Substances* and the *Approved Criteria for Classifying Hazardous*

Substances. Where a substance consists of two or more ingredients, it should be classified as hazardous if:

(a) the whole substance is listed in the *List of Designated Hazardous Substances*

(b) the mixture has been tested as a whole and it satisfies any of the health effects criteria in the *Approved Criteria for Classifying Hazardous Substances*

(c) any of the ingredients of the mixture:

(i) is included in the *List of Designated Hazardous Substances*

(ii) meets any of the health effects criteria,

and is present in the mixture at a concentration which exceeds the relevant cut-off level specified for the hazard classification in the *Approved Criteria for Classifying Hazardous*

- All hazardous substances provided for use at work must be supplied with an MSDS which will be produced by the manufacturer or importer of the substance.

- The Code of practice also lists a number of controls that should be adopted in the workplace to reduce the risk of worker injury during the use of hazardous substances. These controls are outlined as follows:

  If exposure to a hazardous substance cannot be completely eliminated, then consideration should be given to other control measures. According to this report there exists a specific order known as the 'heirarchy of control measures' which should be considered by the employer. These are:

  1. Elimination - eliminating any non-essential workplace hazardous substances
  2. Substitution - substituting the chemical for a less hazardous substance
  3. Isolation - separating people from the process by either distance or barriers.
  4. Engineering controls - Engineering the workplace to make it safer when hazardous substances are being used
  5. Safe Work Practices - administrative processes encouraging people to work in safer ways.
  6. Personal Protective Equipment - Wherever possible, the control of hazardous substances should be secured without the need for personal protective equipment.

Personal equipment should only be used when there are no other safety alternatives, or as an added safety measure when another form of control is being used (NOHSC, 1994, pp49-51).

National Code of Practice for the Labelling of Workplace Substances

Reference: NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC: 2012(1994)] National Occupational Health and Safety Commission, Canberra, AusInfo.

Organization: National Occupational Health and Safety Commission

Importance of Article: This document outlines in detail the labelling standards to be applied to hazardous substances.

Key Points and Important Information:

- The purpose of this code of Practice is to provide a practical guide to the labelling of hazardous substances. The NOHSC acknowledges that information is an essential part of ensuring the safety of workers, and that labels are an imperative part of this communication process.

- Domestic end use products are not covered in this code as they are not used in the workplace. Instead they are covered by the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) under the State and Territories poison legislation.

- In addition to this labelling code, where hazardous substances are also classified as dangerous goods by the Australia Dangerous Goods (ADG) code, the State and Territories dangerous goods codes must also be met (NOHSC, 1994, p3).

- Lead compounds and organometallic lead derivatives are categorized in this code as being part of the Family no. 082, in accordance with section A6.3 and the EEC Directive [67/548/EEC]

Approved Criteria for Classifying Hazardous Substances

Reference: NOHSC (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC: 1008(1999)] National Occupational Health and Safety Commission, Canberra, AusInfo.

Organization: National Occupational Health and Safety Commission

Importance of Article: This publication provides the mandatory criteria for determining whether a substance is hazardous. For the purpose of this report, all the lead compounds that are being researched are already determined as 'hazardous'. Therefore this document is superfluous to this report.

Key Points and Important Information:

- The Classification criteria in this report are the same as those used by the European Communities, namely:
  The EC Council Directive [67/548/EEC3] on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances; and
  The EC Council Directive [88/379/EC4] on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations.

- It is up to the manufacturer or importer to determine whether a substance is hazardous or not. They only need to conduct such a determination if the substance is not previously on the *List of Designated Hazardous Substances* [NOHSC: 10005].

List of Designated Hazardous Substances

Reference: NOHSC (1999) List of Designated Hazardous Substances [NOHSC: 10005(1999)] National Occupational Health and Safety Commission, Canberra, AusInfo. <http//www.nohsc.gov.au/applications/hsis/HSGuidance.htm> Accessed 2005 Aug 25.

Organization: National Occupational Health and Safety Commission

Importance of Article: This list provides the first reference point for importers, manufacturers and suppliers in determining whether a substance is hazardous. It is an important reference for checking which lead compounds are hazardous. Importantly this list has now been superseded by the Hazardous Substances Information System (HSIS) which can be accessed online at http://www.ascc.gov.au/applications/hsis/
This database provides the same information but in a more accessible format.

Key Points and Important Information:

- A concentration cut-off level for a substance in the list represents a level (expressed as a percentage on a weight/weight basis) at and above which that substance must be considered hazardous (NOHSC, 1999, p8).

National Code of Practice for the Preparation of Material Safety Data Sheets

Reference: NOHSC (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC: 2011(1994)] National Occupational Health and Safety Commission, Canberra, AusInfo.

Organization: National Occupational Health and Safety Commission

Importance of Article: This document is very specific in outlining how Material Safety Data Sheets (MSDS) should be written, and what they should include.

Key Points and Important Information:

- The aim of this publication is to provide a practical guidance on meeting the requirements for MSDSs as posed by the *National Model Regulations for the Control of Workplace Hazardous Substances* [NOHSC:1005].

3.2.5 Customs (Prohibited Imports) Regulations 1956

Reference: Customs (Prohibited Imports) Regulations 1956 Statutory Rules 1956 No. 90 as amended made under the Customs Act 1901. This compilation was prepared on 6 December 2005 taking into account amendments up to SLI 2005 No. 279

Organisation: Office of Legislative Drafting and Publishing (OLDP) (2005), Attorney-General's Department, Canberra.

Importance of Article: The Prohibited Imports Regulations apply to a person in Australia or a citizen of Australia who is outside Australia. Chapter 2 of the *Criminal Code* applies to all offences created by these Regulations. It is vital to note the strong feeling of the Australian Paint Manufacturers Federation that many surface coatings that are controlled for lead content by other Australian regulations, are omitted from the Customs (Prohibited Imports) Regulations, thus allowing the import of ítems which are not permitted to be manufactured or for which the lead content is controlled in Australia. Some examples include residential paint, lead paint on furniture, children's playground equipment, mirror-backings, garage doors. It would seem reasonable that any changes to allowable lead content of paints or inks in Australia, should carry on through to Customs (Prohibited Imports) Regulations for example for industrial paints, coatings on

whitegoods and paint on imported vehicles, boats, farm and road-building machinery. Such changes would make any new regulations far more acceptable to the Australian coatings industry.

Key Points and Important Information:

- According to Item 2 of the *Customs (Prohibited Imports) Regulations 1956 Schedule 2*, the importation of toys or playthings coated with a material the non-volatile content of which contains more than 250mg/kg of lead or lead compounds calculated as lead, is prohibited unless the permission in writing of the Minister or an authorised person has been granted.
- According to Item 6 of *Schedule 2*, money boxes coated with a material that contains more than 250mg/kg of lead or lead compounds calculated as lead are similarly prohibited.
- According to Item 7 of *Schedule 2*, pencils or paint brushes coated with a material the non-volatile content of which contains more than 250mg/kg of lead or lead compounds calculated as lead are similarly prohibited.

3.2.6 **Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) No. 20**

Reference: Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) No. 20 Published July 2005, Effective 1st June 2005.

Organization: The National Drugs and Poisons Schedule Committee (NDPSC) (2005) was established under section 52B of the *Therapeutic Goods Act 1989*. The Committee comprises of State and Territory government members and other persons appointed by the federal Minister for Health and Ageing, such as technical experts and representatives of various sectional interests.

Importance of Article: The Decisions of the NDPSC in relation to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) have no force in the Commonwealth law but are recommended for incorporation into State and Territory drugs/poisons legislation. This Standard is invariably referred to in State and Territory legislation in Australia and thus forms the basis of control of lead compounds in paints in this country.

Key Points and Important Information:

- The first classification of lead compounds in the SUSDP is their inclusion in Schedule 4: **Prescription Only Medicine**, or **Prescription Animal Remedy.** The general description of Schedule 4 drugs and poisons is:

  > Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription. (p vii)

  The Schedule 4 listing states:

  > LEAD COMPOUNDS for human therapeutic use **except** when separately specified in these Schedules. (p 108)

- The third classification of lead compounds in the SUSDP is their inclusion in Schedule 6: **Poison.** The general description of Schedule 6 drugs and poisons is:

  > Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label. (p vii)

  The Schedule 6 listing states:

  > LEAD COMPOUNDS **except:**
  >
  > (a) when included in Schedule 4 or 5;
  >
  > (b) in zinc based paints or tinters containing 0.2 per cent or less of lead as an impurity in the zinc and calculated on the non-volatile content of the paint or tinter;
  >
  > (c) in other paints or tinters containing 0.1 per cent or less of lead calculated on the non-volatile content of the paint or tinter;
  >
  > (d) in preparations for cosmetic use containing 100 mg/kg or less of lead;

(e) in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing 100 mg/kg or less of lead; or

(f) in ceramic glazes when labeled with the warning statement: CAUTION – Harmful if swallowed. Do not use on surfaces which contact food or drink.
written in letters not less than 1.5 mm in height. (p 205)

- In other words xxx
- Lead compounds are referred to on pp 108, 166, 205, 274, 301 and 303 of the SUSDP while metallic lead is referred to on page 254. [xxx – Research required to write the key points to be found on these page references and to compile a list including the clause and reference (name of regulation, www.Austlii.edu.au web address and date Accessed) for each State and Territory regulation that refers to the SUSDP in relation to leaded paints]
- The Uniform Paint Standard in the Appendix I provide regulations for adoption by the States and Territories.

1. A person must not manufacture, sell, supply or use a paint containing basic lead carbonate (white lead) except for application as a mirror backing:
(1) containing not more than 15 per cent of lead in the non-volatile content of paint; and
(2) applied not more than 40 microns thick; and
(3) covered by a paint which does not contain lead

3. A person must not manufacture, sell, supply or use a Third Schedule Paint for application to:
(1) a roof or for any surface to be used for the collection or storage of potable water; or
(2) furniture; or
(3) any fence, wall, post, gate, building (interior or exterior), bridge, pylon, pipeline, storage tank or any similar structure; or
(4) any premises, equipment or utensils used for the manufacture, processing, preparation, packing or serving of products intended for human or animal consumption.

4. A person must nor manufacture, sell, supply or use a paint for application to toys unless the paint complies with the specification for coating materials contained in Part 3 of Australian Standard 1647 for Children Toys (Safety Requirements).

   This document has been superseded by AS/NZS ISO 8124.3:2003 Safety of Toys- Migration of Certain Elements

- The Third Schedule of Appendix I states:

  The proportion of a substance for the purposes of this Schedule is calculated as a percentage of the element present in the non-volatile content of the paint

Substance	**Proportion**
LEAD or lead compounds	more than 0.1 per cent
LEAD or lead compounds occurring as an impurity in zinc based paint	more than 0.2 per cent

3.2.7 **Children's Toys (Safety Requirements) - Toxicological Requirements**

Reference: Standards Australia (1995) Children's Toys (Safety Requirements); Part 3: Toxicological Requirements [AS 1647.3]. Available for purchase from <http://www.saiglobal.com/shop> Accessed 2006 Feb 18th.

Organization: Standards Australia is recognized through a Memorandum with the government as the peak non-governmental Australian body involved in the development of standards. Through an active forum of debate, discussion and consensus, it ensures the effective improvement of standards in Australia.

Importance of Article: This document was superseded (by the following document AS/NZS ISO 8124.3) on 23rd May 2003 yet AS 1647.3 is still referred to in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) No. 20 Published July 2005, Effective 1st June 2005 on page 315 – Appendix 1: Uniform Paint Standard.

Key Points and Important Information:

- According to this standard, the maximum acceptable lead migration from toy materials, modeling clay or finger paint is 90 milligrams leachable lead per kilogram of toy material.

3.2.7 **Safety of toys - Migration of certain elements**

Reference: Safety of toys - Migration of certain elements; Part 3: Industrial Applications [AS/NZS ISO 8124.3].

Organization: Standards Australia (2003) (see description of organization in Section 3.2.6 of this report)

Importance of Article: This document superseded the above document (AS 1647.3) on 23rd May 2003. As with any Australian Standard and indeed with the SUSDP itself, which refers to AS 1647.3, this standard, AS/NZS ISO 8124.3, has no legal standing other than that given to it by relevant legislation.

Key Points and Important Information:

- According to this standard, the Maximum acceptable element migration from toy materials for lead is [still] 90 milligrams per kilogram toy material. This includes migration of lead from toy materials and from parts of toys, except materials not accessible and includes the following types of toy materials:
    - Coatings of paints, varnishes, lacquers, printing inks, polymers and similar coatings (see 8.1);
    - Polymeric and similar materials, including laminates, whether textile-reinforced or not, but excluding other textiles (see 8.2);
    - Paper and paper board, up to a maximum mass per unit area of 400 g/m^2 (see 8.3);
    - Natural or synthetic textiles (see 8.4);

- Glass/ceramic/metallic materials, excepting lead solder when used for electrical connections (see 8.5);
- Other materials, whether mass-coloured or not (e.g. wood, fibreboard, hardboard, bone and leather) (8.6);
- Materials intended to leave a trace (e.g. the graphite materials in pencils and liquid ink in pens) (see 8.7);
- Pliable modeling materials, including modeling clays, and gels (see 8.8);
- Paints to be used as such in the toy including finger paints, varnishes, lacquers, glazing powders and similar materials in solid or liquid form (see8.9);

1.3 For the purposes of this part of ISO 8124, the following criteria are considered appropriate in the categorization of toys which can be sucked, licked or swallowed:

- All intended food/oral contact toys, cosmetic toys and writing instruments categorized as toys;
- Toys intended for children up to six years of age, i.e. all accessible parts and components where there is a probability that those parts or components may come into contact with the mouth (see annex D).

Toys and parts of toys which, due to their accessibility, function, mass, size or other characteristics, obviously exclude any hazard due to sucking, licking or swallowing, bearing in mind the normal and foreseeable behaviour of children, are not covered by this part of ISO 8124.

3.2.8 **Guide to Lead Paint Management; Industrial Applications**

Reference: Guide to Lead Paint Management; Part 1: Industrial Applications [AS no. 4361.1].

Organization: Standards Australia (1995) (see description of organization in Section 3.2.6 of this report).

Importance of Article: This document is very specific in its focus on the management of lead-containing paint on industrial structures, however it does provide some relevant information on certain aspects of lead-containing paint used for industrial purposes.

Key Points and Important Information:

- According to this standard, paint is considered to be lead-containing if it contains in excess of 0.1 (*w/w)* lead or lead compounds within the dried film (AS, 1995, p10).

- The standard outlines what form of action is most appropriate in certain situations where lead-containing paint is found on a structure. After evaluating the site, it is important to determine which is best out of the following alternatives: No painting, overcoating, spot of localized repair, total coating removal and replacement, or demolition and replacement of the structure. When making this decision a variety of factors need to be taken into account, including the condition of the coating, the cost of the procedure, the risk to the public and to the workers involved, environmental risks, and the cleaning and clearing techniques to be used on the completion of the project (AS, 1995, pp13-19).

3.2.9 Guide to Lead Paint Management; Residential and Commercial Buildings

Reference: Guide to Lead Paint Management; Part 2: Residential and Commercial Buildings [AS no. 4361.2].

Organization: Standards Australia (1998) (see description of organization in Section 3.2.6 of this report).

Importance of Article: This standard provides guidelines for the management of lead-containing paint on non-industrial structures such as public, residential and commercial

buildings. While it does discuss the increased hazard of public exposure to lead, it deals only minimally with safety procedures for workers.

Key Points and Important Information:

- According to this standard, paint is considered to be lead-containing if it contains in excess of 0.1 *(w/w)* lead or lead compounds within the dried film
- The standard importantly notes that lead in paint only becomes a problem when it is on a friction or impact surface of a building or product, it is deteriorating or it is disturbed by paint removal methods (SA, 1995, p11). When the paint is fully intact, it does not pose a threat to the public's safety.

3.2.10 OH&S Regulations by Australian State and Territory

[xxx – all these references need to be added to Section Three References list and the info in this table should be presented in the Key Points style as above, instead of this table format]

TABLE 8: OH&S Regulations by Australian State and Territory

Clauses of Regulations Relevant to Lead in Surface Coatings and Inks	Relevant Codes of Practice
NEW SOUTH WALES (NSW)	
OHS Regulations 2001 Part 6.4 - USE OF HAZARDOUS SUBSTANCES 161. Application 162. Employer to obtain MSDS 163. Employer to ensure containers are labeled 164. Use of hazardous substances 165. Employer to provide health surveillance 166. Medical practitioner to notify results of health surveillance 167Employer to keep register of hazardous substances 168. Employer to record risk assessments 169. Employer to keep record of employees exposed to carcinogenic substances 170. Employer to provide statement to employees exposed to carcinogenic substances 171. Employer to retain certain material as record	S46 OHS Act 2000 Codes of Practice - Hazardous Substances - list Control of Workplace Hazardous Substances Labeling of Workplace Substances Preparation of Material Safety Data Sheets

172. Medical practitioner to retain records 173. Employer to identify hazardous substances in enclosed systems 174. Employer to provide information to WorkCover and emergency services PART 7.1 - SPRAY PAINTING PART 7.6 - LEAD PROCESSES AND LEAD RISK WORK 199 .Definitions 200. Application 201. Employer to control risks from lead 202. Biological monitoring and health surveillance 203. Employer to remove certain employees from lead risk work 204. Pregnant or breastfeeding employee to advise employer • Cl 346	
QUEENSLAND (QLD)	
Workplace Health and Safety Regulation 1997 Part 13--Hazardous substances Division 1--Interpretation 87. Meaning of exposed 88. Meaning of hazardous substance Division 2--Manufacturers and importers 89. Who division applies to 90. Preparing, amending and reviewing material safety data sheet (“MSDS”) 91. Providing MSDS 92. Notifying use of type 2 ingredient's generic name 93. Disclosing ingredient's chemical name 94. Providing NICNAS summary report and other information • Division 3--Suppliers 95. Who division applies to 97. Providing MSDS 98. Labeling containers • Division 4--Employers and self-employed persons 99. Who division applies to 100. Meaning of hazardous substance for division 101. Obtaining MSDS 102. Recording and displaying MSDS 103. Labeling containers 104. Hazardous substances in enclosed systems 105. Risk assessments 106. Risk assessment records 107. Controlling exposure 108. Monitoring 109. Health surveillance	Hazardous substances

110. Confidentiality of worker's medical record
111. Keeping register
112. Keeping records
113. Induction and training about hazardous substances
114. Prohibited substances and asbestos products

- Division 5--Spray painting with hazardous substances

115A.Ways to prevent or minimise risk prescribed
115B.Manufacturing or importing a spray painting booth
115C.Supplying a spray painting booth
115D.Protecting persons from spray painting
115E.Spray painting to be done in spray painting booth
115F.Controlling exposure from spray painting
115G.Maintaining a spray painting booth
115H.Minimum air movement for booths

Part 14--Lead

Division 1--Interpretation

116. Meaning of exposed
117. Meaning of lead hazardous substance

- Division 2--Manufacturers and importers

118. Who division applies to
119. Preparing, amending and reviewing MSDS
120. Providing MSDS
121. Providing NICNAS summary report and other information

- Division 3--Suppliers

122. Who division applies to
123. Providing MSDS
124. Labeling containers

- Division 4--Employers and self-employed persons

125. Who division applies to
126. Obtaining MSDS
127. Keeping registers
128. Labeling containers
129. Risk assessment
130. Risk assessment records
131. Controlling exposure
132. Atmospheric monitoring
133. Health surveillance
134. Reviewing control measures
135. Removal from a lead-risk job
136. Return to a lead-risk job
137. Confidentiality of worker's medical record
138. Induction and training about lead
139. Keeping records

- Division 5--Workers

140. Who division applies to 141. Health surveillance 142. Advising of pregnancy or breast feeding Part 15--Confined spaces 143. Designing, manufacturing or supplying a confined space 144. Modifying a confined space 145. Using a confined space	
SOUTH AUSTRALIA (SA)	
OCCUPATIONAL HEALTH, SAFETY AND WELFARE REGULATIONS 1995 PART 4--Hazardous substances • Division 4.1--General hazardous substances Subdivision 1--Preliminary 4.1.1. Purpose 4.1.2. Scope 4.1.3. Interpretation Subdivision 2--Supplier's duties 4.1.4. Classification of hazardous substances 4.1.5. Material Safety Data Sheets 4.1.6. Labels 4.1.7. Ingredient disclosure 4.1.8. Provision of other relevant information Subdivision 3--Employer's duties 4.1.9. Material Safety Data Sheets 4.1.10. Labels 4.1.11. Hazardous substances registers 4.1.12. Provision of other relevant information 4.1.13. Prohibition of scheduled substances for specified uses 4.1.14. Instruction and training 4.1.15. Risk assessment 4.1.16. Risk control 4.1.17. Atmospheric monitoring 4.1.18. Health surveillance 4.1.19. Record keeping 4.1.20. Relevant emergency services • **Division 4.3--Lead** 4.3.1. Purpose 4.3.2. The work area 4.3.3. Furniture and equipment	s63 of the *Occupational Health, Safety and Welfare Act 1986* Relatively few codes of practice have been developed specifically for South Australia. Instead the WorkCover Corporation of South Australia has adopted a lot of Standards Australia standards and a few other documents as well as codes of practice.

4.3.4. Control of atmospheric contaminants 4.3.5. Amenities 4.3.6. Safe procedures 4.3.7. Personal protective equipment • **Division 5.8--Spray painting** 5.8.1. Purpose 5.8.2. The work area 5.8.3. Spray booths--construction 5.8.4. Spray booths—exhaust ventilation 5.8.5. Safe working and maintenance procedures 5.8.6. Personal protective equipment	
WESTERN AUSTRALIA (WA)	
Part 5 Interpretation 5.2. Application 5.3Determination of whether or not a substance is a hazardous substance 5.4.Commissioner to be notified of new hazardous substances 5.5.Material Safety Data Sheets 5.6.Labeling etc. 5.7.Commissioner to be notified if generic name used for type II ingredients 5.8.Provision of information about hazardous substances 5.9.Ingredient disclosure to medical practitioners 5.10. Ingredient disclosure to persons who may be affected 5.11. Employers, main contractors and self-employed persons to obtain and provide information 5.12. Duties of employers, main contractors and self-employed persons as to labeling hazardous substances 5.13. Register of hazardous substances 5.14. Certain uses of certain hazardous substances prohibited 5.15. Assessment in relation to hazardous substances 5.16. Assessment report 5.17. Subsequent assessments 5.18. Assessment reports to be available for inspection 5.19. Exposure standards not to be exceeded 5.20. Risks arising from hazardous substances to be reduced and means of reducing risks 5.21. Induction and training 5.22. Monitoring risks associated with hazardous substances 5.23. Health surveillance in relation to hazardous substances 5.24. Duties of appointed medical practitioners 5.25. Employers, main contractors and self-employed persons to take remedial action 5.26. Periods for which records to be kept by employers, main contractors and self-employed persons 5.27. Commissioner to keep certain records as to hazardous substances **Hazardous Substances** 5.28. Definitions 5.29. Concentration of substances for Division 3 to apply 5.30. Commissioner to be informed if carcinogenic substances intended to be used at workplaces 5.31. Schedule 5.4 and 5.6 substances not to be used at workplaces	s 57 of the *Occupational Safety and Health Act 1984* Lead *National Code of Practice for the Control and Safe Use of Inorganic Lead at Work* [NOHSC: 2015 (1994)] Spray Painting The *Code of Practice: Spray Painting*

5.32. Schedule 5.5 substances not to be used at workplaces unless for purpose approved by Commissioner 5.32A Articles containing Schedule 5.6 substances not to be used at workplaces 5.33. Commissioner to acknowledge receipt of notification and information and may impose conditions 5.34. Carcinogenic substances not to be used until conditions set 5.35. Duties of suppliers of carcinogenic substances 5.36. Information for Commissioner to be kept up to date 5.37. Employers and self-employed persons to keep records in relation to carcinogenic substances 5.38. Suppliers to keep records in relation to carcinogenic substances 5.39. Commissioner to keep certain records in relation to carcinogenic substances 5.40. Commissioner to be informed of certain matters as to carcinogenic substances 5.41. Persons who may be exposed to carcinogenic substances to be informed of certain matters **Lead** 5.53. Definitions 5.54. Lead-risk job assessment 5.55. Information for prospective employees 5.56. Health surveillance and counseling 5.57. Assessment of suitability for working in lead-risk jobs 5.58. Induction and training 5.59. Frequency of biological monitoring 5.60. Duties of employers, main contractors and self-employed persons in relation to work with lead 5.61. Duties in relation to working with lead 5.62. Employee to notify if pregnant or breast-feeding 5.63. When person to be removed from lead work 5.64. Return to lead work after removal 5.65. Records in relation to lead 5.66. Commissioner to keep certain records in relation to lead 5.67. Review of decisions concerning lead work	
VICTORIA (VIC)	
OCCUPATIONAL HEALTH AND SAFETY (LEAD) REGULATIONS 2000 PART 1-PRELIMINARY PART 2-EMPLOYER'S DUTIES Division 1-Provision of Information Division 2-Risk Assessment and Control Division 3-Lead-Risk Jobs PART 3-EMPLOYEE DUTIES	s 149 of the *Occupational Health and Safety Act 2004* The *Code of Practice for Lead*

• OCCUPATIONAL HEALTH AND SAFETY (HAZARDOUS SUBSTANCES) REGULATIONS 1999 PART 2-DUTIES WHICH APPLY TO MANUFACTURERS, IMPORTERS AND SUPPLIERS 12 Division 1-General 12 Division 2-Classification of Substances 12 Division 3-Material Safety Data Sheet 13 Division 4-Labels 16 PART 3-DUTIES WHICH APPLY TO EMPLOYERS 20 Division 1-Prohibitions Division 2-Employer's Duties PART 4-ADDITIONAL DUTIES WHICH APPLY TO CARCINOGENIC SUBSTANCES	
AUSTRALIAN CAPITAL TERRITORY (ACT)	
[xxx – research required]	[xxx – research required]
NORTHERN TERRITORY (NT)	
• WORK HEALTH (OCCUPATIONAL HEALTH AND SAFETY) REGULATIONS **PART 7 WORKPLACE** **Division 5 - Hazardous Substances** 66. Classification of hazardous substances 67. Provision of information - supplier's duties 67A. Disclosure of ingredients of hazardous substances 68. Provision of information - employer's duties 69. Prohibition of scheduled substances for specified purposes 69A. Health surveillance 69B. Use of carcinogenic substances 69C. Notification of and consent to use carcinogenic substances 69D. Records 69E. Advice and reporting **Division 6 - Ventilation** 70. Ventilation **Division 7 - Personal Protective Equipment**	s 187A of the *Work Health Act 1986* NT has adopted most of the national codes of practice and also many Standards Australia standards as codes of practice **Inorganic Lead**

PART 12 - SPECIFIC WORK PROCESSES **Division 3 - Spray Painting** 166. Booth required 167. Specifications for booths **Division 5 - Lead** 168A.Biological monitoring 168B.Removal from work	

Codes of Practice

NSW

Section 8(1) of the *Occupational Health and Safety Act 2000* (*OHS Act 2000*) states that as an employer you 'must ensure the health, safety and welfare at work of all the employees.' To meet your responsibilities under the *OHS Act 2000*, you must provide:

- safe premises
- safe machinery and substances
- safe systems of work
- provision of information, instruction, training and supervision
- suitable working environment and facilities.

The Act also states that you are responsible for the health and safety of people other than your workers, who may be present at the workplace.

QLD

In Queensland, s 41- 42 of the *Workplace Health and Safety Act 1995* provides for advisory standards and industry codes of practice to be made as a way of managing exposure to identified risks. The advisory standards tend to apply to risks common in industry in general, whereas the codes of practice tend to be designed for the risk management needs of specific industries. Commencement dates and amendments are announced by publication as subordinate legislation.

Both advisory standards and codes of practice are available from the Workplace Health & Safety division at the Department of Industrial Relations and at the web site www.dir.qld.gov.au/workplace/law/codes/.

SA

In South Australia, sec 63 of the *Occupational Health, Safety and Welfare Act 1986* provides for codes of practice to be made. Codes are approved by the Minister, on the recommendation of the Advisory Committee, and come into operation according to publication in the *South Australian Government Gazette*.

Relatively few codes of practice have been developed specifically for South Australia. Instead the WorkCover Corporation of South Australia has adopted a lot of Standards Australia standards and a few other documents as well as codes of practice.

The codes developed by the WorkCover Corporation are available from them and may also be downloaded from www.workcover.com.

Spray painting

Standards Australia standards adopted as codes of practice for spray painting are the following:

- AS 1715 *Selection, use and maintenance of respiratory protective devices*;
- AS 1716 *Respiratory protective devices*;
- AS 2430 *Classification of hazardous areas*, Part 3 — Specific occupancies; and
- AS 3754 *Safe application of powder coatings by electrostatic spraying*.

WA

In Western Australia, sec 57 of the *Occupational Safety and Health Act 1984* provides for codes of practice to be made. Codes are approved by the Minister, on the recommendation of the Commission for Occupational Safety and Health (previously called the WorkSafe Western Australia Commission), and come into operation according to notice published in the *Western Australian Government Gazette*.

The Western Australian codes of practice are available from WorkSafe WA and from www.safetyline.wa.gov.au.

Lead

The *National Code of Practice for the Control and Safe Use of Inorganic Lead at Work* [NOHSC: 2015 (1994)] was adopted on 10 November 1996.

Spray Painting

The *Code of Practice: Spray Painting* was approved in June 2000. It applies to all workplaces where spray painting is undertaken and to everybody who is potentially exposed to hazards from such work. It should be used by people involved in any aspects of spray painting.

The code focuses on the spray painting process and adopts a risk management approach. Its chapters cover:

- the hazards in spray painting work;
- assessing the risks;
- controlling the risks;
- powder coating;
- provision of information;
- health surveillance; and
- induction and training.

VIC

In Victoria, s 149 of the *Occupational Health and Safety Act 2004* makes provisions for compliance codes to be made by the Minister in order to provide practical guidance for people with safety obligations under the Act. Compliance codes will replace the codes of practice previously approved under s 45 of the repealed *Occupational Health and Safety Act 1985*.

It is anticipated that the compliance codes will be available from the Victorian WorkCover Authority, including its web site www.workcover.vic.gov.au.

The Victorian codes of practice made under the previous legislation will continue to apply to proceedings for an offence against the old Act. The codes are described below. They are presented in groups according to subject areas.

The *Code of Practice on Lead Control* was approved from 1 July 1988. It was replaced from 29 June 2000 by the *Code of Practice for Lead*, developed to provide practical guidance on how to comply with the *Occupational Health and Safety (Lead) Regulations 2000*.

Topics covered by the code include:

- consultation with employees;
- providing information, instruction and training (including in relation to MSDS and labels);
- risk assessment and control, including maintaining the controls;
- ensuring lead exposure standard is not exceeded;
- lead-risk jobs;
- medical examinations and biological monitoring; and
- employees' duties.

Appendixes contain more information about atmospheric monitoring and case studies involving risk assessment and control.

ACT

[xxx – research required]

NT

In the Northern Territory, codes of practice are recommended by the Work Health Authority, approved by the minister as codes of practice according to s 187A of the *Work Health Act 1986* and commence according to publication in the *Northern Territory of Australia Government Gazette*. Codes have also been approved under the *Dangerous Goods Act 1998* and the *Dangerous Goods (Road and Rail Transport) Act 2003*.

The Northern Territory has adopted most of the national codes of practice and also many Standards Australia standards as codes of practice. A complete list of the codes can be found at www.nt.gov.au/deet/worksafe.

The Northern Territory codes of practice are listed below in groups according to subject areas. It should be noted that there is a degree of overlap between some of the general workplace codes and codes listed, for example, under the heading “Construction industry", and also between a few of the codes listed under “Construction industry" (for example those relating to design requirements) and ``Plant". Note that the latter category also takes in plant on a large scale by including major hazard facilities.

Hazardous substances/dangerous goods

The following codes of practice relate to hazardous substances:

• *National Code of Practice for the Control of Workplace Hazardous Substances* [NOHSC: 2007 (1994)]

• *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC: 2011 (1994)]

• *National Code of Practice for the Labeling of Workplace Substances* [NOHSC: 2012 (1994)]

• *National Code of Practice for the Control and Safe Use of Inorganic Lead at Work* [NOHSC: 2015 (1994)]

Hazardous process

Spray painting

The codes relating to spray painting are:

• AS 2268 *Electrostatic paint and powder sprayguns for explosive atmospheres*

• AS 3754 *Safe application of powder coatings by electrostatic spraying*.

[xxx – research required to review and summarise in the style which includes “Key Points and Important Information” as in Section 2 above, the following regulations and other documents and all other relevant Australian state or territory regulations from

www.austlii.edu.au especially Poisons regulations and their connections with the paint clauses in the SUSDP]

- WorkCover NSW (2002) Lead Risk Work, Guidelines for Notification, Government of New South Wales
- Federal Office of Road Safety, (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail, 6th Edition, AusInfo, Canberra.

Other Documents

- APAS (2000) an Explanation of the Australian Paint Approval Scheme D188
- APAS (1999) Some Hazard Aspects of Paint and Painting D129
- Alphen, M (1998) Paint Film Components: National Environmental Health Monographs, General Series No.2 from National Environmental Health Forum <http://enhealth.nphp.gov.au/council/pubs/pdf/paint.pdf> Accessed 2006 Feb 18.

3.3 Regulatory Controls Overseas

[xxx – research required to review and summarise in the style which includes "Key Points and Important Information" as in Section 2 above, the following overseas regulations (ie non-Australian) and any other relevant overseas regulations]

United States of America

3.3.1 Occupational Health and Environmental Control for Lead (Standard Number 1926.62) (USA)

Reference: Substance Data Sheet for Occupational Exposure to Lead [1926.62]

Organization: The Occupational Safety and Health Administration (OSHA) (1993) is xxx

Importance of Article: This article presents a good summary of what is in the standard on Lead [1926.62]

Key Points and Important Information:

- The permissible exposure limit (PEL) outlined in the standard is 50 micrograms of lead per cubic metre of air (50 ug/m(3)), averaged over an 8 hour workday (OSHA, 1993, p1).
- If an employee is working in an environment where the lead level is at or above 30 micrograms of lead per cubic metre of air 30 ug/m(3)) averaged over an 8 hour working day, then the "Action Level" has been reached and certain provisions must be met by the employer including exposure monitoring, medical surveillance and training (OSHA, 1993, p1).
- The data sheet asserts that "Inhalation of airborne lead is generally the most important source of occupational lead absorption" (OSHA, 1993, p2).
- According to the standard, the fact sheet notes that a worker's blood lead level be maintained at or below forty micrograms per deciliter of whole blood (40 ug/dl) OSHA, 1993, p2).
- As the report notes, not only does lead poisoning have the capacity to affect reproductive organs in women, but it also affects men; "Chronic overexposure to lead impairs the reproductive systems of both men and women. Overexposure to lead may result in decreased sex drive, impotence and sterility in men." The standard takes into account this hazard and states that so as to avoid any adverse reproductive health effects, the blood lead level of those workers with the desire to have children should be at or below 30 micrograms per deciliter of whole blood (30 ug/dl) (OSHA, 1993, p1&2).

3.3.2 Ban of Lead Containing-Paint and Certain Consumer Products Bearing Lead-Containing Paint [Part 1303] (USA)

Reference: Ban of Lead Containing-Paint and Certain Consumer Products Bearing Lead-Containing Paint [Part 1303] from *The Consumer Product Safety Act* Code of Federal Regulation, Title 16, Volume 2

Organization: The Consumer Products Safety Commission (1994) is an independent regulatory agency that was formed in 1973, under the Consumer Products Safety Act. The purpose of the commission includes protecting the public against any unreasonable risks of injury associated with consumer products, assisting consumers in evaluating the safety of products, developing uniform safety standards for consumer products and conducting research into the causes of any health hazards posed by these products.

Importance of Article: This is a very important article as it outlines the ban placed on products containing lead-based paint in the American consumer market.

Key Points and Important Information:

- 1303.1: Under sections 8&9 of the Consumer Product Safety Act (CPSA), any paints or surface coatings that contain lead (calculated as lead metal) in excess of 0.6 percent of the total non-volatile content of the paint or the weight of the dried paint film are banned (CPSC, 2004, p376).
- Also banned under this act are:
    - Any toys or other items intended for use by children that contain 'lead-containing paint' (as specified above).
    - Any furniture articles for consumer use that bear 'lead-containing paint'.
    - Any product bearing 'lead containing paint' that is intended for use as consumables, for the enjoyment of consumers in or around the household, in schools or for recreation purposes are also covered by this regulation (CPSC, 2004, p376).
- Auto products and boat paints are not included in this ban as they are outside of the statutory definition for what is considered a 'consumer product'

- In addition to the products aforementioned which are sold directly to consumers, the ban also relates to products used by consumers after sale, including:
    - "Paints used in residences, schools, hospitals, parks, playgrounds and public buildings" (CPSC, 2004, p376).
    - Any other areas where consumers will have direct access to the painted surface
- Products exempt from this ban include:
    - Agricultural and industrial equiptment refinish coating
    - Industrial and Commercial building and equiptment maintanence coatings including those used for traffic lights and safety markings.
    - Graphic arts coatings, such as products marketed for billboards and roadsigns.
    - Touchup coatings for agricultural equipment, garden and lawn equipment and appliances.
    - Catalyzed coatings marked soley for use on radio-controlled, model powered aircraft (CPSC, 2004, p378).
    - These products are required to bear on the main panel of their labelling, in adition to any other labels that may apply, the words: "WARNING: Contains Lead. Dried film of this Paint may be Harmful if Eaten or Chewed." They must also bear the following additional statement or its practical equivelant:

      > "Do not apply on toys and other children's articles, furniture, or interior surfaces of any dwelling or facility which may be occupied or used by children.
      >
      > Do not apply on exterior surfaces of dwelling units, such as window sills, porches, stairs, or railings, to which children may be commonly exposed."
      >
      > (CPSC, 2004, p377)

- Other products exempt from the ban that do not need to display warning labels

include:

- Mirrors that contain lead containing back paint and are part of a furntiture article
- Artists' paints and related material
- Metal furniture articles that bear factory applied lead coatings (CPSC, 2004, p378).

3.3.3 Lead Toxicity: Standards and Regulations (USA)

Reference: Lead Toxicity, Standards and Regulations.

Organization: The Agency for Toxic Disease Registry (ATSDR) (2005) is an agency of the US Department of Health and Human Services. It's goal is to "serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related to toxic substances" (ATSDR, 2005).

Importance of Article: This article is a great secondary literature source as it summarizes all the important regulations regarding lead that have been put in place in the United States.

Key Points and Important Information:

- This ATSDR report uses a table to explain the different regulations in place in America in regards to lead. This table is summarized in TABLE 9 below.

TABLE 9: Summary of ATSDR's Table of USA Lead Regulations

Agency	Media	Level	Comments

Centers for Disease Control and Prevention (CDC)	Blood	10 µg/dL	Level of concern for children
Occupational Safety and Health Administration (OSHA)	Blood	40 µg/dL 50 µg/dL	Cause for written notification and medical exam Cause for medical removal from exposure
	Air (workplace)	50 µg/m^3 30 µg/m^3	Permissible exposure limit (8-hr average) (general industry) Action level
National Institute for Occupational Safety and Health (NIOSH)	Air (workplace)	50 µg/m^3 100 mg/m^3	Recommended exposure limit (nonenforceable) Immediately dangerous to life and health
American Conference of Governmental Industrial Hygienists (ACGIH)	Air (workplace)	150 µg/m^3 50 µg lead/m^3	LV/TWA guideline for lead arsenate TLV/TWA guideline for other forms of lead
	Blood	30 µg/dL	Biological exposure index
US Environmental Protection Agency (EPA)	Air (ambient)	1.5 µg/m^3	National Ambient Air Quality Standard; 3-month average
	Soil (residential)	400 mg/kg	Soil screening guidance
	Water (drinking)	15 µg/L 0 µg/L	Action level for public supplies Nonenforceable goal; maximum contaminant level goal
Food and Drug Administration (FDA)	Food	Various	Action levels for various foods; example: lead-soldered food cans now banned

Consumer Product Safety Commission (CPSC)	Paint	600 ppm[§] (0.06%)	Calculated by dry weight

Where:

µg/dL: micrograms per deciliter.
µg/m^3: micrograms per cubic meter.
TLV/TWA: threshold limit value/time-weighted average.
ppm: parts per million.

(Table taken from ATSDR (2005) *Lead Toxicity, Standards and Regulations* with minor alterations)

[OTHER US DOCUMENTS TO BE ANALYSED USING KEY POINTS STYLE XXX]

- CPSC (date? xxx) Guidance for Lead (Pb) in Consumer Products <http://www.cpsc.gov/businfo/leadguid.html> Accessed 2005 Aug 25.
- CPSC (1998) Codification of Guidance Policy on Lead in Consumer Products, [Federal Register: December 22, 1998 (Volume 63, Number 245)] [Rules and Regulations] [Page 70648-70649] <http://www.cpsc.gov/businfo/frnotices/fr99/lead.html> Accessed 2005 Aug 25.
- EPA (Environmental Protection Agency) (1996) Part XI: Lead; Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities; Final Rule [40 CFR Part 745] the Environmental Protection Agency
- EPA (1998) Evaluating and Controlling Lead-Based Paint Hazards: A Guide for Using EPA's Lead Based Paints Hazard Standards, Public Review Draft, the Environmental Protection Agency
- EPA (1998) Part II: Management and Disposal of Lead-Based Paint Debris; Proposed Rule and Temporary Suspension of Toxicity Characteristic Rule for Specified Lead-Based Paint Debris; Proposed Rule, Federal Register **63**(243) pp7019-70233
- EPA (2001) Part III: Lead; Identification of Dangerous Levels of Lead; Final Rule [40 CFR Part 745]

- EPA (2005) Lead in paint, Dust, and Soil <http://www.epa.gov/lead>. Accessed 2005 Aug 25.
- Lutter, R (2001) Getting the Lead out Cheaply: a review of the EPA's proposed residential lead hazard standards, Environmental Science and Policy 4 pp13-21
- NIOSH (1992) Preventing Lead Poisoning in Construction Workers [DHSS (NIOSH) Publication No. 91-116a] The National Institute of Occupational Health and Safety
- NIOSH (1997) Protecting Workers Exposed to Lead-Based Paint Hazards: a Report to Congress [DHHS (NIOSH) publication No. 98-112] The National Institute of Occupational Health and Safety
- OSHA (1998) Lead: Toxic and Hazardous Substances [1910.1025] Occupational Safety and Health Administration
- OSHA (1998) Lead: Occupational Health and Environmental Controls [1926.62] Occupational Safety and Health Administration
- OSHA (Occupational Safety and Health Administration) (2005) Controlling Lead Exposures in the Construction Industry: Engineering and Work Practice Controls, OSHA Technical Manual Section V Chapter 3 <http://www.osha.gov/dts/osta/otm/otm_v/otm_v_3.html>. Accessed 2005 Sep 5.
- SHARP (Safety and Health Assessment and Research for Prevention), Department of Labor and Industries (1999) Occupational Lead Exposure: An Alert for Workers
- US Congress (1992) Residential Lead-Based Paint Hazard Reduction Act of 1992--Title X <http://www.hud.gov/offices/lead/regs/leatilex.pdf> Accessed 2006 Feb 22.

European Union

3.3.xxx **Directive Relating to Dangerous Substances and Preparations (EU)**

Reference: Council Directive of 27 July 1976 [76/769/EEC] on the approximation of the laws, regulations and administrative provisions of the Member States relating to the

restrictions on the marketing and use of certain dangerous substances and preparations. Last amended 30 September 2004 <http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1976/L/01976L0769-20041018-en.pdf> Accessed 2006 Feb 26.

Organisation: Council of the European Communities (CEC)

Importance of Article: These European Union Council Directives in relation to lead in paints seem heavily oriented towards heritage issues.

Key Points and Important Information:

- According to the amendment brought about by the Council Directive of 21 December 1989, the neutral anhydrous carbonate of lead, Pb CO3, CAS No 598-63-0, and trilead-bis(carbonate) dihydroxide, 2 Pb CO3-Pb (OH)2, CAS No 1319-46-6, may not be used as substances and constituents of preparations intended for use as paints, except for the restoration and maintenance of works of art and historic buildings and their interiors, where Member States wish to authorize this on their territory, in accordance with the provisions of ILO Convention 13 on the use of white lead in paint.
- Similarly, and brought about by the same amendment, Lead sulphates, PbSO4 (1:1), CAS No 7446-14-2 Pbx SO4, CAS No 15739-80-7 May not be used as substances and constituents of preparations intended for use as paints, except for the restoration and maintenance of works of art and historic buildings and their interiors, where Member States wish to authorize this on their territory, in accordance with the provisions of ILO Convention 13 on the use of sulphates of lead in paint.
- The Appendix lists xxx

[xxx – other overseas regulations regarding lead in paint to be reviewed:]

- EEC (1994) Council Directive [67/548/EEC] on the Approximation of Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labelling of Dangerous Substances [Directive (EC) No. 1488/94] <http://ecb.jrc.it/classification-labelling/>. Accessed 2005 Oct 15 and <http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31967L0548&model=guichett> Accessed 2006 Feb 26.
- EEC (1994) Annex 1 to Council Directive [67/548/EEC] http://72.14.207.104/search?q=cache:YXm3w4XUyVMJ:www.unitar.org/cwm/ghs_library/Documents/cat3/EC_Dir_67_548_annex1_en.pdf+67/548/EEC+%22Annex+1%22&hl=en&ct=clnk&cd=1 Accessed 2006 Feb 26.
- The EC Council Directive [88/379/EC4] on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations.
- EEC (2004) Council Directive of 27 July 1976 [76/769/EEC] on the approximation of the laws, regulations and administrative provisions of the Member States relating to the restrictions on the marketing and use of certain dangerous substances and preparations. Last amended 30 September 2004 <http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1976/L/01976L0769-20041018-en.pdf> Accessed 2006 Feb 26.

United Kingdom

- HMSO (2002) Health and Safety: The Control Of Lead at Work Regulations, Statutory Instrument No. 2676, Her Majesty's Stationary Office
- PRA (2005) SHE Alert, Bulletin 121, Coatings Technology Centre, pp3-34
- PRA (2005) Coatings, Regulations and the Environment (CORE), Coatings Technology Centre **14**(5) pp1-25

3.3.xxx **Other International Documents**

- Fleischer, M (2003) Regulation and Innovation in the Chemical Industry: A comparison of the EU, Japan and the USA, Surface Coatings International Part B: Coatings Transactions **86**(B1) pp1-90
- ILO (1980) Occupational exposure to Airborne Substances Harmful to Health [ISBN 92-2-102442-3] the International Labor Organization
- OECD (1993) Lead: Background and National Experience with Reducing Risk, Organization for Economic Co-operation and Development, Paris
- OECD (2003) Guiding Principles for Chemical Accident Prevention, Preparedness and Response: guidance for industry (including management and labour), public authorities, communities and other stake holders, Organization for Economic Co-operation and Development, Paris.

SECTION THREE REFERENCES

- ATSDR (Agency for Toxic Substances and Disease Registry) (2005) Lead Toxicity, Standards and Regulations <http://www.atsdr.cdc.gov/HEC/CSEM/lead/standards_regulations.html> Accessed 2006 Mar 7.
- Consumer Products Safety Commission (CPSC) (2004) Ban of Lead Containing-Paint and Certain Consumer Products Bearing Lead-Containing Paint [Part 1303] from *The Consumer Product Safety Act* Code of Federal Regulation, Title 16, Volume 2 <http://www.cpsc.gov/businfo/regsumlead**paint**.pdf> Accessed 2006 Mar 7.
- Council of the European Communities (CEC) (2004) Council Directive of 27 July 1976 [76/769/EEC] on the approximation of the laws, regulations and administrative provisions of the Member States relating to the restrictions on the marketing and use of certain dangerous substances and preparations. Last amended 30 September 2004 <http://europa.eu.int/eur-

lex/lex/LexUriServ/site/en/consleg/1976/L/01976L0769-20041018-en.pdf> Accessed 2006 Feb 26.

- CPSC (Consumer Protection Safety Commission) (2004) Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint [part 1303] Consumer Products Safety Commission <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=ac28c3043de5406883867a0e6d92963e&rgn=div5&view=text&node=16:2.0.1.2.45&idno=16> Accessed 2006 Mar 7.
- NOHSC (1994b) National Code of Practice for the control and Safe Use of Inorganic Lead at work [NOHSC: 1012(1994)] National Occupational Health and Safety Commission, Canberra, AusInfo. <www.nohsc.gov.au/ohslegalobligations/nationalstandards/lead.htm> Accessed 2005 Nov 18.
- NOHSC (1994c) National Model Regulations for the Control of Workplace Hazardous Substances [NOHSC: 1005 (1994)] National Occupational Health and Safety Commission, Canberra, AusInfo. <http://www.worksafe.gov.au/PDF/Standards/WorkplaceHazardousSubstances-model_regs_NOHSC1005_1994.pdf> Accessed 2005 Nov 18.
- Office of Legislative Drafting and Publishing (OLDP) (2005), Attorney-General's Department, Canberra. Customs (Prohibited Imports) Regulations 1956 Statutory Rules 1956 No. 90 as amended made under the Customs Act 1901. This compilation was prepared on 6 December 2005 taking into account amendments up to SLI 2005 No. 279 <http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/0/5DF04CA3536C5076CA2570CE007D5618/$file/CustomsProhImport1956_WD02.pdf> Accessed 2006 Feb 19.
- OSHA (1993) Substance Data Sheet for Occupational Exposure to Lead - 1926.62 App A. 57 FR 26627, May 4, 1993, as amended at 58 FR 34218, June 24, 1993 <www.hud.gov/offices/lead/regs/1962_62.pdf> Accessed 2006 Mar 7.
- Standards Australia (1998) Guide to Lead Paint Management; Part 2: Residential and Commercial Buildings [AS no. 4361.2]. Available for purchase from <http://www.saiglobal.com/shop> Accessed 2006 Feb 18.

- Standards Australia (2003) Safety of toys - Migration of certain elements; Part 3: Industrial Applications [AS/NZS ISO 8124.3]. Available for purchase from <http://www.saiglobal.com/shop> Accessed 2005 Dec 12.
- The National Drugs and Poisons Schedule Committee (NDPSC) (2005) Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) No. 20 Published July 2005, Effective 1st June 2005. Available for purchase from <http://www.tga.gov.au/ndpsc/susdp.htm>. Accessed 2005 Dec 7th.
- The National Occupational Health and Safety Commission (NOHSC) (1994a) National Standard for the control of Inorganic Lead at work [NOHSC:1012(1994)] National Occupational Health and Safety Commission, Canberra, AusInfo. <www.nohsc.gov.au/ohslegalobligations/nationalstandards/lead.htm> Accessed 2005 Nov 18.
- WorkCover Authority NSW (2001) Part 7.6 Lead processes and lead risk work, EXTRACT from OHS Regulation 2001 With Margin Notes p 168 <http://www.workcover.nsw.gov.au/NR/rdonlyres/C0BDD17A-386F-47F1-8C49-278E6BA2E4C7/0/reg_ohs_02_margin_108.pdf> Accessed 2006 Feb 18.
- xxx

4. VOLUNTARY INDUSTRY CONTROLS AFFECTING SURFACE COATINGS AND INKS

4.1 Voluntary Industry Controls in Australia

4.1.1 Paint Manufacturing in Australia

Reference: Paint Manufacturing in Australia (C2542) in IBIS world industry report

Organization: IBIS World (2005) provides extensive information on every industry in Australia for the purposes of strategic planning and research.

Importance of Article: While the IBIS World report talks in detail about the nature of the market which is not of any particular importance to the current report, it also provides a useful insight into the paint industry in Australia. As a large part of the current report involves researching industry initiatives for regulatory controls on the use of lead in paint, the information provided in this report is useful and up to date.

Key Points and Important Information:

- According to the IBIS World report, the primary activities of firms in the paint industry are manufacturing:
  - Caulking compound
  - Filler or putty
  - Lacquer
  - Paint mfg (except bituminous)
  - Paint or varnish remover, prepared,
  - Paint tinting colour, prepared,
  - Primer or undercoat, paint,
  - Rubbing compound

- Stain
- Wood stain (packed for sale)

  This list is useful as it suggests that the paint industry is not involved just in paint, but also in the manufacture of other surface coatings.

- The report goes on to state that the major products and services in this industry are:
  - Architectural & decorative paints, enamels & clears
  - Industrial paints, enamels & clears
  - Thinners
  - Heavy duty coatings
  - Timber finishes (IBIS World, 2005, p3)

- Also included is a section on regulation and deregulation on the industry. Here it is noted that Worksafe Australia (now called ASCC) administers the National Model Regulations and Code of Practice for the chemical industry. The regulation, according to the report "underpins occupational health and safety in relation to plant and equipment, hazardous substances, transport and storage and labeling of chemicals within the industry" (IBIS world, 2005, p14).

- The report also asserts that on top of Worksafe Australia, there are a number of other self regulated associations and schemes that address health, safety and environmental issues. One of these is the Australian Paints Manufacturer's Federation (APMF) which acts as a primary interface between paint manufacturers, the Governments and the public in regards to issues impacting the manufacture, supply and use of surface coatings. The APMF represents over 98 percent of Australia's coatings manufacturing capacity and has established four Coatings Care Codes of Practice; a Manufacturing Management Code, the Packaging, Storage and Distribution Code, the Product Stewardship Code and the Community Responsibility Code (IBIS world, 2005, p15).

- Importantly the report labels the main industries involved in paint manufacture in Australia, including Orica Limited (with the various brand names of Dulux, British

Paints, Berger, Walpamur) who own 25% of the total Market Share, Watyll Limited with 19% of market share, Barloworld Australia Pty Limited (with the brand names Taubmans and Bristols) who have a 9% share in the market and Akzo Nobel Industries Limited who have 6% market share. PPG Industries Australia Pty Ltd was also mentioned in this report, however its market share was not noted. These names are important as the project involves finding industry initiatives in regards to regulations for the use of lead. It will be important to make contact with these industry representatives so as to see what regulations they adhere to, and if any initiatives have been taken.

Other References on Voluntary Industry Controls in Australia

[xxx - Research required to review and summarise (as above) the following Australian and overseas industry documents and any other relevant documents you can find]

- APMF (2003) Product Stewardship (PS) Code, Coatings Care, Australian Paint Manufacturer's Federation
- APMF (2003) Community Responsibility (CR) Code, Coatings Care, Australian Paint Manufacturer's Federation
- APMF (2003) Guidance on Community Responsibility Code, Coatings Care, Australian Paint Manufacturer's Federation
- APMF (2003) Transport and Distribution Code and Guidance, Coatings Care, Australian Paint Manufacturer's Federation
- Environment Australia (in consultation with APMF, MPA et al) Lead Alert - The Six Step Guide To Painting Your Home - Second Edition

4.2 Voluntary Industry Controls Overseas

- NPCA (National Paints and Coatings Association, USA) (2000) The Paint and Coatings Industry Addresses Lead Issue, Issue Backgrounder **8**(4) pp1-8
- NPCA (2001) The Paint and Coatings Industry Focuses on Occupational Health and Safety with its Hazardous Materials identification Scheme, Issue Backgrounder **9**(1) pp1-4
- NPCA (2004) Getting the Word Out: NPCA's Lead Exposure Warnings, Education and training Programs, Issue Backgrounder **12**(2) pp1-4
- BCF (2005) Old Lead Painted Surfaces: a guide on repainting and removal for D-I-Y and professional painters and decorators, British Coatings Federation

SECTION FOUR REFERENCES

- IBIS World (2005) Paint Manufacturing in Australia (C2542) in IBIS world industry report http://www.**ibisworld**.com.au/**industry**/definition.asp?**industry**_id=187 Accessed 2005 Nov 18.

5. REGULATIONS AFFECTING COSMETICS AND TOILETRIES

[xxx – research required to review and summarise (as above) the following overseas regulations (ie non-Australian) and any other relevant overseas regulations]

5.1 Regulatory Controls in Australia

Commonwealth

5.1.1 Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) No. 20

Reference: NDPSC (National Drugs and Poisons Schedule Committee) (2005) Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) No. 20 Published July 2005, Effective 1st June 2005. Available for purchase from <http://www.tga.gov.au/ndpsc/susdp.htm>. Accessed 2005 Dec 7th.

Organization: The National Drugs and Poisons Schedule Committee (NDPSC) was established under section 52B of the *Therapeutic Goods Act 1989*. The Committee comprises of State and Territory government members and other persons appointed by the federal Minister for Health and Ageing, such as technical experts and representatives of various sectional interests.

Importance of Article: The Decisions of the NDPSC in relation to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) have no force in the Commonwealth law but are recommended for incorporation into State and Territory drugs/poisons legislation. This Standard is invariably referred to in State and Territory legislation in Australia and thus forms the basis of control of lead compounds in cosmetics in this country.

Key Points and Important Information:

- As noted earlier, the first classification of lead compounds in the SUSDP is their inclusion in Schedule 4: **Prescription Only Medicine**, or **Prescription Animal Remedy.** The general description of Schedule 4 drugs and poisons is:

  > Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription. (p vii)

  The Schedule 4 listing states:

  > LEAD COMPOUNDS for human therapeutic use **except** when separately specified in these Schedules. (p 108)

- The second classification of lead compounds in the SUSDP is their inclusion in Schedule 5: **Caution.** The general description of Schedule 5 drugs and poisons is:

  > Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

  The Schedule 5 listing states:

  > LEAD COMPOUNDS in preparations for use as hair cosmetics. (p 166)

- The third classification of lead compounds in the SUSDP is their inclusion in Schedule 6: **Poison.** The general description of Schedule 6 drugs and poisons is:

  > Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label. (p vii)

  The Schedule 6 listing states:

  > LEAD COMPOUNDS **except:**
  >
  > (g) when included in Schedule 4 or 5;
  >
  > (h) in zinc based paints or tinters containing 0.2 per cent or less of lead as an impurity in the zinc and calculated on the non-volatile content of the paint or tinter;
  >
  > (i) in other paints or tinters containing 0.1 per cent or less of lead calculated on the non-volatile content of the paint or tinter;
  >
  > (j) in preparations for cosmetic use containing 100 mg/kg or less of lead;

(k) in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing 100 mg/kg or less of lead; or

(l) in ceramic glazes when labeled with the warning statement: CAUTION – Harmful if swallowed. Do not use on surfaces which contact food or drink.
written in letters not less than 1.5 mm in height. (p 205)

- It is contradictory for LEAD COMPOUNDS to be included in both Schedule 5 (low potential for causing harm) and Schedule 6 (moderate potential for causing harm) and it would appear more appropriate to list the specific lead compounds in one or the other schedule depending on whether they have a low or a moderate potential for causing harm.

Lead compounds are referred to on pp 108, 166, 205, 274, 301 and 303 of the SUSDP while metallic lead is referred to on page 254. [xxx – Research required to write the key points to be found on these page references and to compile a list including the clause and reference (name of regulation, www.Austlii.edu.au web address and date Accessed) for each State and Territory regulation that refers to the SUSDP in relation to leaded cosmetics]

5.1.2 Trade Practices Act

Reference: xxx

Organisation: xxx

Importance of Article: In Australia, product safety and product information are governed by both Commonwealth and State legislation. Product safety standards generally set down minimum safety standards, while product information standards generally require sellers to provide certain information about a product.

Key Points and Important Information:

- At the federal level, the *Trade Practices Act* provides for consumer product safety standards, product information standards and notices warning the public of goods that are under investigation. Under the Act the Minister is empowered to declare certain goods to be unsafe goods or order the mandatory recall of unsafe goods supplied after 1 July 1986.
- With the adoption of uniform State fair trading legislation mirroring the consumer protection provisions of the *Trade Practices Act*, some of the States have adopted product safety provisions modelled on the *Trade Practices Act*, including the recall of unsafe or defective goods.
- Item 3 of the *Regulations* Schedule 2 lists the importation of cosmetics products
- Part V Div 1A contains sec 65B- 65T of the *Trade Practices Act 1974* relates to product safety and product information.
- Section 65B provides for the publication of various warning notices by the Minister in the *Gazette* in relation to potentially injurious goods.
- Consumer product safety standards, unsafe goods declarations and banning orders are dealt with in sec 65C. Consumer product information standards are outlined in sec 65D. In addition to the formulation of new standards, existing safety and information standards may be adopted and declared by the Minister, and this course is outlined in sec 65E.
- The new area of compulsory product recall is dealt with in sec 65F, and sec 65G covers compliance with such orders. A deeming provision in sec 65H is concerned with loss or damage suffered as a result of non-compliance with a compulsory recall order.
- Conferences may be held before the finalisation of certain decisions under the Part, and the provisions dealing with these conferences are contained in sec 65J-65Q. Conferences may also be held following the declaration that goods are unsafe (sec 65M).
- Currently, there are no safety standards set for cosmetics and toiletries in regards to lead content and there are no cosmetics or toiletries banned under the *Trade Practices Act* 1974.

5.1.3 Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991

Reference: Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 Statutory Rules 1991 No. 327 as amended made under the Trade Practices Act 1974. Compilation prepared 28 Sep 2004 taking into account amendments up to SR 1998 No. 364

Organisation: Office of Legislative Drafting, Attorney-General's Department, (2004) Canberra, Commonwealth of Australia.

Importance of Article: All cosmetics and toiletries products manufactured and intended to be used in Australia or imported into Australia must be labelled in accordance with the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991. All suppliers, including manufacturers, importers, wholesalers and retailers, must ensure that their product complies with the mandatory information standard.

Key Points and Important Information:

- Cosmetic and toiletry products are substances or preparations intended for placement in contact with any external part of the body, including the mouth and the teeth with a view to:
  - altering the odours of the body; or
  - changing its appearance; or
  - cleansing it; or
  - maintaining it in good condition; or
  - perfuming it; or
  - protecting it.

These include:

- creams, emulsions, lotions gels or oils for the skin;
- face masks; make-up, after-bath or hygiene powders;
- deodorants;
- handcleansers;
- hand protection creams;
- hair-care products including:
    - hair tints or bleaches;
    - products for waving, straightening or fixing hair;
    - setting products including lotions, creams or oils;
- tainted bases including liquids, powders or pastes.

- The mandatory information standard requires the product ingredients be listed on the container or the product itself, if not packed in a container.

- According to s5(2) the ingredients are to be listed in descending order calculated by either mass or volume. Alternatively, ingredients can be listed in the following order:
    - ingredients (not colour additives) in concentrations of 1 per cent or more – in descending order by volume or mass, and
    - ingredients (not colour additives) in concentrations of less than 1 per cent – in any order; and
    - colour additives – in any order

- The mandatory information standard does not require the quantity or percentage of each ingredient to be listed.

5.1.4 **Customs (Prohibited Imports) Regulations 1956**

Reference: Customs (Prohibited Imports) Regulations 1956 Statutory Rules 1956 No. 90 as amended made under the Customs Act 1901. This compilation was prepared on 6 December 2005 taking into account amendments up to SLI 2005 No. 279

<http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/0/5DF04CA3536C5076CA2570CE007D5618/$file/CustomsProhImport1956_WD02.pdf> Accessed 2006 Feb 19.

Organisation: Office of Legislative Drafting and Publishing (OLDP) (2005), Attorney-General's Department, Canberra.

Importance of Article: The Prohibited Imports Regulations apply to a person in Australia or a citizen of Australia who is outside Australia. Chapter 2 of the *Criminal Code* applies to all offences created by these Regulations.

Key Points and Important Information:

- The Minister can also declare goods to be prohibited imports under the *Customs (Prohibited Imports) Regulations*, although this does not debar goods manufactured in or already imported into Australia.
- Item 3 of the *Regulations* Schedule 2 lists the importation of cosmetics products containing more than 250mg/kg of lead or lead compounds (calculated as lead), except products containing more than 250mg/kg of lead acetate designed for use in hair treatments, as prohibited unless the permission in writing of the Minister or an authorised person has been granted..

States and Territories

A variety of State legislation deals with safety and information standards and this applies (unless it is not possible) concurrently with the federal provisions. As well as some specific product safety legislation, the States have legislated in such areas as food and drugs, poisons, protection from injury (particularly from electrical injury), information about textiles, footwear and furniture, information about agricultural products and chemicals, packaging and labelling, and weights and measures.

Queensland

Part IV, Div 1 provides that information standards for specified goods or services may be prescribed by regulation. Regulations have been made in relation to cosmetics.

> Section 82 of the *Fair Trading Act* provides that a person shall not supply goods or services to a consumer unless the prescribed information standard is complied with. Further, if goods or services are supplied without compliance and suffers loss or damage because of the lack of information the person who suffered the loss or damage is deemed to have suffered it by the supply of the goods or services.

Bans

Goods that may cause injury to a person can be declared unsafe by the minister by notice in the Commonwealth Gazette. Goods will then be banned from supply for 18 months unless the declaration is revoked before the end of that time or the goods are permanently banned. The ACCC enforces bans on unsafe goods.

5.2 Regulatory Controls Overseas

United States of America (USA)

The Food, Drug, and Cosmetic Act requires that cosmetics and their individual ingredients must be safe and that labelling must be truthful and not misleading. The Food and Drug Administration's (FDA) legal authority over cosmetics is comparable with its authority over other FDA-regulated products, such as foods, non-prescription drugs, and non-

prescription medical devices. FDA can take immediate action to stop the sale of any product that does not meet these standards.

Consumers can have confidence in their cosmetics given their oversight by FDA and long history of safe use.

5.2.1 **Prohibited Ingredients and Related Safety Issues (USA)**

Reference: Prohibited Ingredients and Related Safety Issues, March 30, 2000; Revised May 2005 <http://www.cfsan.fda.gov/~dms/cos-210.html> Accessed 2006 Feb 23.

Organisation: Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition (CFSAN), US Food and Drug Administration (FDA)

Importance of Article: Prohibited Ingredients and Related Safety Issues is a factsheet to assist in understanding what FDA does and does not regulate in terms of cosmetics ingredients and labelling.

Key Points and Important Information:

- By law, FDA does not have the authority to approve cosmetic products or ingredients, except for color additives. However, regulations prohibit or restrict the use of several ingredients because of safety concerns. Lead compounds are not one of these ingredients.
- Because lead compounds are not one of the prohibited or restricted ingredients (except as color additives – see below), the FDA control of lead in cosmetics comes down to the following statement: ‘It is the responsibility of the manufacturer and distributor to assure the safety of each ingredient and finished product. Without substantiation of safety, Title 21 of the Code of Federal Regulations (21 CFR), Part 740.10 requires that the product carry the following warning on the label: **"Warning: The safety of this product has not been determined."’**

- Color additives are strictly regulated. In order to protect consumers from harmful contaminants, many cannot be used unless the color comes from a batch certified by FDA and that batch is provided with its own individual certification lot number. Their uncertified counterparts are not allowed and addition of the color to a product will make the entire product adulterated. While colors exempt from certification are not subject to such testing, manufacturers must assure that each color additive complies with the identity, specifications, labeling requirements, use, and restrictions of color additive regulations. With the exception of coal-tar hair dyes, all color additives - whether or not they are subject to certification - must be approved by FDA for their intended use.
- The risk of introducing contaminants into a product is always a concern in cosmetic manufacture, whether they are introduced through contaminated raw ingredients or form during the manufacturing process.

5.2.2 **Color Additives Approved for Use in Cosmetics: exempt from batch certification (USA)**

Reference: Color Additives Approved for Use in Cosmetics: Part 73, Subpart C: Color additives exempt from batch certification, from Summary of Color Additives Listed for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices, Content last updated 1st Sept 2005 <http://www.cfsan.fda.gov/~dms/opa-col2.html#table3A> Accessed 2006 Feb 23.

Organisation: CFSAN (Center for Food Safety and Applied Nutrition), FDA (Food & Drug Administration), DHHS (Department of Health & Human Services)

Importance of Article: This Summary of those cosmetics colour additives that are approved in the US but are exempt from batch certification is important in that lead acetate is the only lead compound approved as a colour additive and the voluntary codes of many other countries rely on the FDA regulations.

Key Points and Important Information:

- Lead acetate was approved in 1981 as a colour additive for "Cosmetics intended for coloring hair on the scalp only, NTE [not to exceed] 0.6 percent (weight/volume)."
- Of the other 28 colour additives approved for cosmetics and exempt from batch certification, some are permitted to contain up to 10 parts per million lead while most are permitted to contain up to 20 parts per million lead. See lists at Section 5.2.4.

5.2.3 Listing of Color Additives Exempt from Certification: Lead Acetate (USA)

Reference: Part 73 -- Listing of Color Additives Exempt from Certification: Subpart C -- Cosmetics: Sec. 73.2396 Lead acetate 31st October 1980 <www.cfsan.fda.gov/~lrd/cf732396.html> Accessed 2006 Feb 23.

Organisation: FDA (Food & Drug Administration), DHHS (Department of Health & Human Services)

Importance of Article: The listing of Lead Acetate in these US Federal Regulations, in 1980 has probably influenced the legislation of every other country since then until recent times.

Key Points and Important Information:

- The color additive lead acetate is the trihydrate of lead (2+) salt of acetic acid.
- The color additive lead acetate may be safely used in cosmetics intended for coloring hair on the scalp only, subject to the following restrictions: (1) The amount of the lead acetate in the cosmetic shall be such that the lead content, calculated as Pb, shall not be in excess of 0.6 percent (weight to volume). (2) The cosmetic is not to be used for

coloring mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp.

- The label of the color additive lead acetate shall conform to the requirements of Sec. 170.25 of this legislation, and bear the following statement or equivalent: **"Wash thoroughly if the product comes into contact with the skin."**
- The label of the cosmetic containing the color additive lead acetate, in addition to other information required by the act, shall bear the following cautionary statement, conspicuously displayed thereon: **"CAUTION: Contains lead acetate. For external use only. Keep this product out of children's reach. Do not use on cut or abraded scalp. If skin irritation develops, discontinue use. Do not use to color mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp. Do not get in eyes. Follow instructions carefully and wash hands thoroughly after each use."**

5.2.4 Listing of Color Additives Exempt from Certification (USA)

Reference: Part 73--Listing of Color Additives Exempt from Certification, Chapter I--Food And Drug Administration, Department Of Health And Human Services, Title 21--Food And Drugs, Code of Federal Regulations, Revised as of April 1st, 2002 <http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr73_02.html> Accessed 2006 Feb 23.

Organisation: FDA (Food & Drug Administration), DHHS (Department of Health & Human Services)

Importance of Article: It is only by going to these actual regulations that you can find the lead limits allowed in these colour additives approved subject to batch certification. The lead limit here of 20 parts per million seems to be popular in the voluntary codes and / or regulations of many other countries.

Key Points and Important Information:

- Specifications such as lead limits are to be applied with Good Manufacturing Practice (GMP)
- The following FDA approved colours are permitted to contain up to 10 parts per million lead as lead:
    - Annatto,
    - Caramel,
    - Carmine,
    - beta-Carotene,
    - Silver and
    - Titanium dioxide.
- And the remaining (following) are permitted to contain up to 20 parts per million lead as lead:
    - Bismuth citrate,
    - Disodium EDTA copper,
    - Potassium sodium copper chlorophyllin (Chlorophyllin copper complex),
    - Dihydroxyacetone,
    - Bismuth oxychloride,
    - Guaiazulene,
    - Henna,
    - Iron oxides,
    - Ferric ammonium ferrocyanide,
    - Chromium hydroxide green,
    - Guanine,
    - Pyrophyllite,
    - Mica,
    - Aluminum powder,
    - Bronze powder,
    - Copper powder,
    - Ultramarines (blue, green, pink, red, and violet)
    - Manganese violet,

- Zinc oxide and
- Luminescent zinc sílfide.

5.2.5 Color Additives Approved for Use in Cosmetics subject to batch certification (USA)

Reference: Color Additives Approved for Use in Cosmetics: Part 74, Subpart C: Color additives subject to batch certification, from Summary of Color Additives Listed for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices, Content last updated 1st Sept 2005 <http://www.cfsan.fda.gov/~dms/opa-col2.html#table3B> Accessed 2006 Feb 23.

Organisation: CFSAN (Center for Food Safety and Applied Nutrition), FDA (Food & Drug Administration), DHHS (Department of Health & Human Services)

Importance of Article: This Summary of those cosmetics colour additives that are approved in the US but subject to batch certification is important in that no lead compound is listed and all the additives go by the names of colours, like red or blue.

Key Points and Important Information:

- There are 35 colour additives approved for cosmetics and subject to batch certification, none of which has lead in the name.
- Some are permitted to contain up to 10 parts per million lead while most are permitted to contain up to 20 parts per million lead. See lists at Section 5.2.6.

5.2.6 Listing of Color Additives Subject to Certification (USA)

Reference: Part 74--Listing of Color Additives Subject to Certification, Chapter I--Food And Drug Administration, Department Of Health And Human Services, Title 21--Food And Drugs, Code of Federal Regulations, Revised as of April 1st, 2002

<http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr74_02.html> Accessed 2006 Feb 23.

Organisation: FDA (Food & Drug Administration), DHHS (Department of Health & Human Services)

Importance of Article: It's only by going to the actual regulations that you can find the lead limits for colour additives approved subject to batch certification. The voluntary codes of many other countries rely on the FDA regulations.

Key Points and Important Information:

- Specifications such as lead limits are to be applied with Good Manufacturing Practice (GMP).
- The following colours with lead limits of 10 parts per million (as lead) are approved subject to batch certification:
  - D&C Black No. 2,
  - FD&C Blue No. 1,
  - FD&C Green No. 3,
  - FD&C Red No. 4,
  - FD&C Red No. 40,
  - FD&C Yellow No. 5, and
  - FD&C Yellow No. 6.
- The following colours with lead limits of 20 parts per million (as lead) are approved subject to batch certification:
  - D&C Blue No. 4,
  - D&C Brown No. 1,
  - D&C Green No. 5,
  - D&C Green No. 6,
  - D&C Green No. 8,
  - D&C Orange No. 4,

- D&C Orange No. 5,
- D&C Orange No. 10,
- D&C Orange No. 11,
- D&C Red No. 6,
- D&C Red No. 7,
- D&C Red No. 17,
- D&C Red No. 21,
- D&C Red No. 22,
- D&C Red No. 27,
- D&C Red No. 28,
- D&C Red No. 30,
- D&C Red No. 31,
- D&C Red No. 33,
- D&C Red No. 34,
- D&C Red No. 36,
- D&C Violet No. 2,
- Ext. D&C Violet No. 2,
- D&C Yellow No. 7,
- Ext. D&C Yellow No. 7,
- D&C Yellow No. 8,
- D&C Yellow No. 10, and
- D&C Yellow No. 11.

- As an example of the manufacturing process of one of these dyes, the leuco base of FD&C Blue No. 1 is oxidized with lead dioxide and acid, or with dichromate and acid, or with manganese dioxide and acid to form the dye. FD&C Blue No. 1 shall conform in specifications to the requirements of Sec. 74.101(b) and may be safely used for coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice (GMP).

European Union

5.2.7 Directive Relating to Cosmetic Products (EU)

Reference: COUNCIL DIRECTIVE of 27 July 1976, on the approximation of the laws of the Member States relating to cosmetic products, (76/768/EEC), (OJ L 262, 27.9.1976, p. 169). Last amended 28th January 2005.

Organisation: Council of the European Communities (CEC)

Importance of Article: The European Union's Council Directives on the approximation of the laws of the Member States relating to cosmetic products

Key Points and Important Information:

- "Lead and its compounds" are included in Annex II of the Directive – the List of Substances which Must Not Form Part of the Composition of Cosmetic Products.
- According to the Directive, "A 'cosmetic product' shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition."
- Article 1, Point 2 states that "the products to be considered as cosmetic products within the meaning of this definition are listed in Annex I."

5.2.8 Directive Relating to Dangerous Substances and Preparations (EU)

Reference: Council Directive of 27 July 1976 [76/769/EEC] on the approximation of the laws, regulations and administrative provisions of the Member States relating to the restrictions on the marketing and use of certain dangerous substances and preparations.

Organisation: Council of the European Communities (CEC)

Importance of Article: The European Union's Council Directives on the approximation of the laws, regulations and administrative provisions of the Member States relating to the marketing and use of certain dangerous substances and preparations, which gives their restrictions.

Key Points and Important Information:

- Substances, that are classified as carcinogen category 1 [currently the only Lead compound in this category is Lead hydrogen arsenate (CAS No. 7784-40-9)] and labelled as T [Toxic] with Risk phrase R45 [May cause cancer by inhalation], may not be used in substances and preparations placed on market for sale to the general public in individual concentration equal or greater than either the concentration specified in Annex I to Council Directive 67/548/EEC or the concentration specified in point 6, Table VI, of Annex I to Council Directive 88/379/EEC, where no concentration limit appears in Annex I to Directive 67/548/EEC.
- Substances, that are classified as carcinogen category 1 [e.g. Lead hydrogen arsenate (CAS No. 7784-40-9)] and labelled as T [Toxic] with Risk phrase R45 [May cause cancer by inhalation], must be marked legibly and indelibly as follows: 'Restricted to professional users'.
- By the way of derogation, this provision shall not apply to cosmetic products as defined by Council Directive 76/768/EEC
- Substances, that are classified as toxic to reproduction category 1 (see TABLE 10 below) and labelled with Risk Phrase R60 [May impair fertility] and/or R61 [May cause harm to unborn child], may not be used in substances and preparations placed on market for sale to the general public in individual concentration equal

or greater than either the concentration specified in Annex I to Council Directive 67/548/EEC or the concentration specified in point 6, Table VI, of Annex I to Council Directive 88/379/EEC, where no concentration limit appears in Annex I to Directive 67/548/EEC

- Substances, that are classified as toxic to reproduction category 1 and labelled with Risk Phrase R60 [May impair fertility] and/or R61 [May cause harm to unborn child], must be marked legibly and indelibly as follows: 'Restricted to professional users'.
- By the way of derogation, this provision shall not apply to cosmetic products as defined by Council Directive 76/768/EEC

From 76/769/EEC Appendix Annex I

TABLE 9: Lead Chemicals listed under Carcinogens: Category 1 (EU)

Compound	**CAS Number**
lead hydrogen arsenate	7784-40-9

TABLE 10: Lead Chemicals Listed Under Toxic for Reproduction: Category 1 (EU)

Compound	**CAS Number**
lead hexafluorosilicate	25808-74-6
lead compounds with the exception of those specified elsewhere in this Annex	Various
lead alkyls	Various
lead azide	13424-46-9
lead chromate	7758-97-6
lead di(acetate)	301-04-2
trilead bis(orthophosphate)	7446-27-7
lead acetate	1335-32-6

lead(II) methanesulphonate	17570-76-2
C.I. Pigment Yellow 34; (This substance is identified in the Colour Index by Colour Index Constitution Number, C.I. 77603.)	082-009-00-X
C.I. Pigment Red 104; (This substance is identified in the Colour Index by Colour Index Consititution Number, C.I. 77605.)	082-010-00-5
lead hydrogen arsenate	7784-40-9
lead 2,4,6-trinitroresorcinoxide, lead styphnate	15245-44-0

- The CMR substance list in Annex I to Directive 67/548/EEC is reproduced in Annex I to Directive 76/769/EEC**.** Some of the substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1 and 2 under Annex I to Directive 67/548/EEC (whereby those which relate to lead have been represented in Tables 9 and 10) are said to be not yet listed in Annex II to Directive 76/768/EEC on prohibited substances. (Commission Directive 2005/80/EC (21 November 2005).
- According to this, this means that whichever lead compounds appear on this CMR list, may, or may not, form part of the list considered to be prohibited lead compounds.
- In other words, the lead compounds that are mentioned in other parts of this Annex (i.e. throughout Annex I), possibly occur in cosmetics, but might or might not be encompassed by the statement that describes the Annex II conditions in the Cosmetics Directive (76/768/EEC).
- Lead componds that are listed in the Annex I to 67/548/EEC, but which are not listed in Annex I or II of 76/768/EEC or any of its updates, might also occur in cosmetics, and since Annex I to 67/548/EEC is stated to not apply to cosmetics, (i.e. “by the way of derogation, this provision shall not apply to cosmetic products

as defined by Council Directive 76/768/EEC") it is unclear whether or not the lead compounds that are listed here do form part of the prohibited Annex II list of lead compounds, especially since not all from Annex I have yet been listed into Annex II.

- This list applies to the marketing and use of dangerous substances, which relates to cosmetics, however, Annex I of the "Council Directive relating to cosmetic products" (76/768/EEC) does not have its own list somewhere of correlating compounds of specifically identified lead compounds that are permitted, and/or prohibited, besides lead acetate, which is permitted with certain restrictions.
- Annex I of the Council Directive relating to cosmetic products is an "Illustrative List by Category of Cosmetic Products". Instead of listing chemicals, it lists product types which are cosmetics.
- There is no other Annex that states that those compounds that are listed in Annex I of 67/548/EEC , and that do not appear yet in Annex I or Annex II of 76/768/EEC, are not allowed in Cosmetics.
- Of importance elsewhere in Annex I of Council Directive (76/768/EEC), Lead carbons, and Lead sulphates, are listed as dangerous substances numbers seventeen and eighteen, as follows:

  17. Lead carbons:

  − neutral anhydrous carbonate ($PbCO_3$ [CAS No 598-63-0])

  − C1 trilead-bis(carbonate)-dihydroxide ($2PbCO_3$-$Pb(OH)_2$ [CAS No 1319-46-6])

  "May not be used as substances and constituents of preparations intended for use as paints, except for the restoration and maintenance of works of art and historic buildings and their interiors, where Member States wish to authorize this on their territory, in accordance with the provisions of ILO Convention 13 on the use of white lead in paint."

  18. Lead sulphates

  PbSO4 (1:1) [CAS No 7446-14-2]

  Pbx SO4 [CAS No 15739-80-7]

"May not be used as substances and constituents of preparations intended for use as paints, except for the restoration and maintenance of works of art and historic buildings and their interiors, where Member States wish to authorize this on their territory, in accordance with the provisions of ILO Convention 13 on the use of sulphates of lead in paint. (Directive 76/769/EEC)."

- These two qualify as "appearing elsewhere" in this Annex, (table 10 includes "lead compounds, with the exception of those specified elsewhere in this Annex"), but although they are an exception to this CMR classification and restriction levels, nothing else is mentioned about their CMR nor of their restrictions as applicable to cosmetics.
- Since restrictions are made for lead and lead compounds, but exempt those that are mentioned elsewhere in the Annexes, these two lead compounds that are mentioned in Annex I of 76/769/EEC are an exemption, and appear with no other prohibition, restrictions or concentration levels.
- As can be ascertained from the History section, lead sulphates and lead carbons are components in many cosmetic products.
- In the Directive, they are listed as Liquid Substances or Preparations that are dangerous in accordance to Article 2 (2) of the Council Directive of 21 December 1989 amending Directive 76/769/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Official Journal L 398, 30/12/1989 P. 0019 – 0023, (89/677/EEC).
- Their criteria are also in Annex VI, Part II of this Directive.
- The List of dangerous substances, contained in Annex I to Directive 67/548/EEC (the Substances Directive) is a list of substances for which harmonized classification and labelling have been agreed with at Community level, in accordance with the procedure laid down in the Directive (Article 4(3)). However, according to legislation this system should not be applied to cosmetics, since they have their own specifications and requirements for labelling, even though set requirements for these compounds do not appear anywhere.

5.2.9 The EU Council Directive on packaging and labelling of dangerous substances (EU)

Reference: Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196 , 16/08/1967, pages 0001 - 0098 (DE, FR, IT, NL)
Organisation: The Council of the European Economic Community

Importance of Article: Covers laws, regulations, and administrative provisions relating to the classification, packaging, and labelling of dangerous substances. Council Directive (67/548/EEC of 27 June 1967).

Key Points and Important Information:

- It is the main source of European Union law concerning chemical safety.
- The Council Directive (1967) does not cover Cosmetics, however, the Council Directive 76/768/EEC was adopted to cover Cosmetics on 27 July 1976.
- Annex I of Council Directive 67/548/EEC of 27 June 1967 defines the c/m/r-classification applicable to the substances appearing in the Annex of Directive 76/768/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances.
- Substances which have previously been listed as carcinogen, mutagen or toxic to reproduction (c/m/r) in Annex I of Council Directive 67/548/EEC of 27 June 1967 (on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances) have been placed into the Annex I of 76/769/EEC.
- Some of the lead compounds listed here may occur in cosmetics, and in thus listing the different lead compounds that exist as dangerous substances, that might

be consulted when identifying which compounds involve “lead and lead compounds” referred to in Annex II, which are otherwise not identified elsewhere.

- Annex I of the 67 Directive is available as OJ of the European Committees, No C 34 of 7 April 1972, page 11.
- For example, one version, The Commission Directive 2000/32/EC of 19 May, 2000, lists “Lead sufochromate yellow”, and “Lead chromate molybdate sulfate red”.
- This 1967 Annex does not apply to cosmetics, so unless these compounds are included in the Cosmetics Directive, these compounds are not considered. It is therefore unclear whether these are permitted, and/or prohibited.
- CMR for lead compounds in cosmetics are in Tables 9 and 10 and lead chromate is CMR cat 1 Toxic for Reproduction. Lead sulfate and lead chromate, impose CMR category 1 concentrations. Appearing in Annex IC of the 67 Directive as Lead sufochromate yellow, and Lead chromate molybdate sulfate red, these compounds as “lead chromate compounds” may possibly be permitted.
- The substances that comprise Annex I of the Cosmetics Directive (76/768/EEC) are to be found at 94/60/EC, which is continually updated. It is unclear whether the compounds here are yet to be included into the Annex II of the Cosmetics Directive (76/768/EEC).
- 94/60/EC replaces Articles 1-23 of Directive 67/548/EEC, and contains the updates to Annex I (76/769/EEC)
- Foreword to Annex 1A, under the heading “Groups of substances,” the following information is stated:

  In some cases, there are classification and labeling requirements for specific substances that would be covered by the group entry. In such cases a specific Annex I entry will be present for the substance and the group entry will be annotated with the phrase “except those specified elsewhere in this Annex”.
- Individual substances may also in some cases be covered by more than one group entry. To this, the Foreword to Annex A states:

Lead oxalate (Einecs No 212-413-5) is for instance covered by the entry for lead compounds (index No 082-001-00-6) as well as for salts of oxalic acid (607-007-00-3). In these cases, the labelling of the substance reflects the labelling for each of the two group entries. In cases where different classifications for the same hazard are given, the classification leading to the more severe classification is used for the label of the particular substance. (OJ L 225/4 21.08.2001)

5.2.10 The European Parliament and Council Directive Marketing and Use of Dangerous Substances (EU)

Reference: European Parliament and Council Directive 94/60/EC amending for the fourteenth time Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.

Organisation: The Council of the European Economic Community

Importance of Article: Amends the Directive for Marketing and Use of Dangerous Substances and Preparations.

Key Points and Important Information:

- This is the reference for referring to the aforementioned Annex I, the amending reference that replaces Article 1 – 27 of the 67/548/EEC Annex I, that is to be continually updated.
- It contains Annex I to 76/769/EEC, which occurs as a list of category 1 or 2 carcinogens, mutagens or substances toxic to reproduction (c/m/r), continually updated by way of adaptation to technical progress.
- It is important to follow the amendments as of (94/60/EC) because they keep track of the updated versions of Annex I considered relevant to the two directives relating to The Dangerous Substances Directive, (67/548/EEC) and (76/769/EEC), to which Lead and Lead compounds would periodically apply.

- Even though the Dangerous Substance Directive (76/769/EEC) does not apply to cosmetics, it contains a list of lead compounds in the Annex with (c/m/r) categorizations, indicating their hazards, and thus their assumed suitability for use in cosmetics.

5.2.11 Directive of the European Parliament and of the Council Amendments (EU)

Reference: Directive 2005/90/EC of the European Parliament and of the Council of 18 January 2006 amending, for the 29th time, Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (substances classified as carcinogenic, mutagenic or toxic to reproduction — c/m/r) Official Journal L 033, 04/02/2006 P. 0028 – 0081

Organisation: European Parliament and Council of the European Union.

Importance of Article: Outlines the amendments made in 2005 since the adaptation of 94/60/EC to the Dangerous Substances Directive (76/769/EEC) and its Annexes.

Key Points and Important Information:

- Point number 5 states, that in the list under heading “Point 31 - Toxic to reproduction: category 1”, the entry with index number 082-001-00-6 is replaced by “Lead compounds with the exception of those specified elsewhere in the Annex I of Dir 67/548/EEC”.
- The entry with index number 082-002-00-1 is replaced by “Lead alkyls”
- Again, by consulting Annex I of Dir 67/548/EEC, a list of lead compounds may be found that indicates specifically which compounds would be exempt from the CMR classification “Toxic to Reproduction: Category 1”, some of which might occur in cosmetics, but have not been given restriction levels, concentration

levels, or prohibitions by occurring in a list that specifically prohibits the substance.

5.2.12 The Council Directive on Obligation for Dangerous Substances Classification Directive (EU)

Reference: The Three yearly report on the implementation of Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances, as amended by Directive 92/32/EEC

Organisation: The Council of the European Communities

Importance of Article: Reporting obligation for Dangerous Substances Classification Directive 67/548/EEC.

Key Points and Important Information:

- This article incorporates the 7th AMENDMENT of 1992 that has been made to (67/548/EEC)**,** requiring that the principles of risk assessment for 'new' substances be laid down. The obligation occurs as Council Directive (76/769/EEC).
- The 1992 seventh amendment replaces article 1-23 of this Directive (67/548/EEC), obligating Member States to inform the Commission and other Member States about new substances by forwarding to the Commission a report on the implementation of this Directive in their respective territories.
- For the latest reporting, a questionnaire, asking for qualitative as well as quantitative aspects of the national implementation of the Directive was sent by the Commission to all the Member States and to Norway.
- The first report of 1998 is available as The Three yearly report on the implementation of Directive 67/548/EEC on the classification, packaging and labeling of dangerous substances, as amended by Directive 92/32/EEC.

- In implementing the Reporting Obligation Directive, the Three Yearly Report outlines how a questionnaire was instituted, demanding certain knowledge such as a description of the administrative system in each Member State, the way in which Directive 67/548/EEC and its amendments have been implemented in national legislation (laying down the principles of risk assessment, and the information request on polymers), co-operation and information exchange in practice, and any issues that arose out of implementing this Directive.
- It is known that Each Safety Data Sheet that is required for Lead as part of complying with this obligation may be obtained from the ROD website for each country.
- The two amendments include Directive 93/67/EEC (laying down the principles of risk assessment), and Directive 93/105/EEC laying down the information requirements on polymers).
- As stated in Article 2 of The Reporting Directive, "This Directive shall not apply to the following preparations in the finished state, intended for the final user: (b) cosmetic products defined by Directive 76/768/EEC, as last amended by Directive 86/199/EEC". Therefore cosmetic manufacturers are not obligated to submit to this reporting obligation, and do not use the questionnaire.

5.2.13 Prohibited Substances and Marketing of cosmetics (EU)

Reference: The rules governing cosmetic products in the European Union, Volume 1 Cosmetics legislation Cosmetic products (1999)

Organization: European Commission

Importance of Article: A Copy of the Cosmetics Directive 76/768/EEC published in 1999 with amendments. Article 4 relates directly to prohibited substances in cosmetics. Apart from listing the rules for "prohibited substances", the document also continues to list the rules regarding the labeling of cosmetics.

Key Points and important information:

- Article 4 of the Directive states:

  Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing of cosmetic products containing:

  (a) substances listed in Annex II;

  (b) substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down;

  (c) colouring agents other than those listed in Annex IV, Part 1, with the exception of cosmetic products containing colouring agents intended solely to colour hair;

  (d) colouring agents listed in Annex IV, Part 1, used outside the conditions laid down, with the exception of cosmetic products containing colouring agents intended solely to colour hair;

  (e) preservatives other than those listed in Annex VI, Part 1;

  (f) preservatives listed in Annex VI, Part 1, beyond the limits and outside the conditions laid down, unless other concentrations are used for specific purposes apparent from the presentation of the product;

  (g) UV filters other than those listed in Part 1 of Annex VII;

  (h) UV filters listed in Part 1 of Annex VII, beyond the limits and outside the conditions laid down therein;

  (i) ingredients or combinations of ingredients tested on animals after 30 June 2000 in order to meet the requirements of this Directive. (page 8)

- 2. The presence of traces of the substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 2. (European Commission, 1999, pages 7-8)
- Again, in Annex II of The European Cosmetic Directive “lead and lead compounds” is specifically listed as part of the “List of substances which must not form part of the composition of cosmetic products.” (European Commission, 1999)

- This list begins on page 17, whereby “lead and lead compounds, with the exception of that mentioned in Annex III, No 55 under the conditions stated” features as substance number 289. (European Commission 1999)
- In Annex III Part 1 of the Cosmetic Directive, “List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down,” No. 55 is Lead acetate, specified with the following on page 49:

  Reference number: 55

  Substance: Lead acetate

  Field of application and/or use: Only for hair dyeing

  Maximum authorized concentration in the finished cosmetic product: 0.6 % calculated in lead

  Other limitations and requirements: (none)

  Conditions of use and warnings which must be printed on the label:

  — Keep away from children

  — Avoid all contact with the eyes

  — Wash hands after use

  — Contains lead acetate

  — Do not use to dye eyelashes, eyebrows or moustaches

  — If irritation develops, discontinue use

- Article 5

  Member States shall allow the marketing of cosmetic products containing:

  (a) the substances listed in Annex III, Part 2, within the limits and under the conditions laid down, up to the dates in column (g) of that Annex;

  (b) the colouring agents listed in Annex IV, Part 2, within the limits and under the conditions laid down, until the admission dates given in that Annex;

  (c) the preservatives listed in Annex VI, Part 2, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex. However, some of these substances may be used in other concentrations for specific purposes apparent from the presentation of the product;

  (d) the UV filters listed in Part 2 of Annex VII, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex.

At these dates, these substances, colouring agents, preservatives and UV filters shall be:

— definitively allowed, or

— definitively prohibited (Annex II), or

— maintained for a given period specified in Part 2 of Annexes III, IV, VI and VII, or

— deleted from all the Annexes, on the basis of available scientific information or because they are no longer used.

Article 5a

1. No later than 14 December 1994 the Commission shall, under the procedure laid down in Article 10, compile an inventory of ingredients employed in cosmetic products, on the basis in particular of information supplied by the industry concerned.

For the purposes of this Article “cosmetic ingredient” shall mean any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of cosmetic products.

The inventory shall be divided into two sections: one concerning perfume and aromatic raw materials and the second concerning other substances.

2. The inventory shall contain information on:

— the identity of each ingredient, in particular its chemical name, the CTFA name, the European Pharmacopoeia name, the international non-proprietary names recommended by the World Health Organisation, the EINECS, IUPAC, CAS and colour index numbers, and the common name referred to in Article 7 (2),

— the usual function(s) of the ingredient in the final product,

— where appropriate, restrictions and conditions of use and warnings which must be printed on the label by reference to the Annexes.

3. The Commission shall publish the inventory and shall update it periodically under the procedure provided for in Article 10. The inventory shall be indicative and shall not constitute a list of the substances authorized for use in cosmetic products.

Article 6

1. Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and packaging bear the following information in indelible, easily legible and visible lettering; the information mentioned in point (g) may, however, be indicated on the packaging alone:

(a) the name or style and the address or registered office of the manufacturer or the person responsible for marketing the cosmetic product who is established within the Community. Such information may be abbreviated in so far as the abbreviation makes it generally possible to identify the undertaking. Member States may require that the country of origin be specified for goods manufactured outside the Community;

(b) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five millilitres, free samples and single-application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. This information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;

(c) the date of minimum durability. The date of minimum durability of a cosmetic product shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with Article 2.

The date of minimum durability shall be indicated by the words: “Best used before the end of ... ” followed by either:

— the date itself, or

— details of where the date appears on the packaging.

If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

The date shall be clearly expressed and shall consist of the month and the year in that order. Indication of the date of durability shall not be mandatory for cosmetic products the minimum durability of which exceeds 30 months;

(d) particular precautions to be observed in use, especially those listed in the column “Conditions of use and warnings which must be printed on the label” in Annexes III, IV, VI and VII, which must appear on the container and packaging, as well as any special precautionary information on cosmetic products for professional use, in particular in hairdressing. Where this is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain that information to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the container and the packaging;

(e) the batch number of manufacture or the reference for identifying the goods. Where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging;

(f) the function of the product, unless it is clear from the presentation of the product;

(g) a list of ingredients in descending order of weight at the time they are added. That list shall be preceded by the word “ingredients”. Where that is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain the ingredients to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the packaging.

The following shall not, however, be regarded as ingredients:

— impurities in the raw materials used,

— subsidiary technical materials used in the preparation but not present in the final product,

— materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions.

Perfume and aromatic compositions and their raw materials shall be referred to by the word “perfume” or “flavour”. Ingredients in concentrations of less than 1% may be listed in any order after those in concentrations of more than 1%. Colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination adopted in Annex IV.

For decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the terms “may contain” are added.

An ingredient must be identified by the common name referred to in Article 7 (2) or, failing that, by one of the names referred to in Article 5a (2), first indent.

In accordance with the procedure laid down in Article 10, the Commission shall, no later than 14 December 1994, adopt the criteria and conditions under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the abovementioned list.

Where it is impracticable, for reasons of size or shape, for the particulars referred to in points (d) and (g) to appear in an enclosed leaflet, those particulars shall appear on a label, tape or card which is enclosed or attached to the cosmetic product.

In the case of soap, bath balls and other small products where it is impracticable, for reasons of size or shape, for the particulars referred to in point (g) to appear on a label, tag, tape or card or in an enclosed leaflet, those particulars shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.

2. For cosmetic products that are not pre-packaged, are packaged at the point of sale at the purchaser's request, or are pre-packaged for immediate sale, Member States shall adopt detailed rules for indication of the particulars referred to in paragraph 1.

3. Member States shall take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have. Furthermore, any reference to testing on animals must state clearly whether the tests carried out involved the finished product and/or its ingredients.

Article 7

1. Member States may not, for reasons related to the requirements laid down in this Directive and the Annexes thereto, refuse, prohibit or restrict the marketing of

any cosmetic products which comply with the requirements of this Directive and the Annexes thereto.

2. They may, however, require that the particulars provided for in Article 6 (1) (b), (c), (d) and (f) be expressed at least in their own national or official language or languages; they may also require that the particulars provided for in Article 6 (1) (g) be expressed in a language easily understood by the consumer. To that end, the Commission shall adopt a common ingredients nomenclature in accordance with the Article 10 procedure.

3. Furthermore, a Member State may, for purposes of prompt and appropriate medical treatment in the event of difficulties, require that appropriate and adequate information on substances used in cosmetic products be made available to the competent authority, which shall ensure that that information is used only for the purposes of such treatment.

Each Member State shall designate a competent authority and send details thereof to the Commission, which shall publish that information in the Official Journal of the European Communities.

Article 7a

1. The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6 (1) (a): (a) the qualitative and quantitative composition of the product; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier;

(b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;

(c) the method of manufacture complying with the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned; the person responsible for manufacture or first importation into

the Community must possess an appropriate level of professional qualification or experience in accordance with the legislation and practice of the Member State which is the place of manufacture or first importation;

(d) assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure. Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be kept available. In this connection, and when so requested for monitoring purposes, he shall be obliged to indicate the place so chosen to the monitoring authority/authorities concerned;

(e) the name and address of the qualified person or persons responsible for the assessment referred to in (d). That person must hold a diploma as defined in Article 1 of Directive 89/48/EEC in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline;

(f) existing data on undesirable effects on human health resulting from use of the cosmetic product;

(g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product.

2. The assessment of the safety for human health referred to in paragraph 1 (d) shall be carried out in accordance with the principle of good laboratory practice laid down in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances.

3. The information referred to in paragraph 1 must be available in the national language or languages of the Member State concerned, or in a language readily understood by the competent authorities.

4. The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member

State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products before the latter are placed on the Community market.

5. Member States shall designate the competent authorities referred to in paragraphs 1 and 4 and shall send details thereof to the Commission, which shall publish that information in the Official Journal of the European Communities.

6. The Member States shall ensure that the abovementioned authorities continue to cooperate in areas where such cooperation is necessary to the smooth application of this Directive.

Article 8

1. In accordance with the procedure laid down in Article 10 the following shall be determined:

— the methods of analysis necessary for checking the composition of cosmetic products,

— the criteria of microbiological and chemical purity for cosmetic products and methods for checking compliance with those criteria.

2. The common nomenclature of ingredients used in cosmetic products and, after consultation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, the amendments necessary for the adaptation to technical progress of the Annexes shall be adopted in accordance with the same procedure, as appropriate.

Article 8a

1. Notwithstanding Article 4 and without prejudice to Article 8 (2), a Member State may authorize the use within its territory of other substances not contained in the lists of substances allowed, for certain cosmetic products specified in its national authorization, subject to the following conditions:

(a) the authorization must be limited to a maximum period of three years;

(b) the Member State must carry out an official check on cosmetic products manufactured from the substance or preparation use of which it has authorized;

(c) cosmetic products thus manufactured must bear a distinctive indication which will be defined in the authorization.

2. The Member State shall forward to the Commission and to the other Member States the text of any authorization decision taken pursuant to paragraph 1 within two months of the date on which it came into effect.

3. Before expiry of the three-year period provided for in paragraph 1, the Member State may submit to the Commission a request for the inclusion in a list of permitted substances of the substance given national authorization in accordance with paragraph 1. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which the substance or preparation is intended. Within 18 months of submission of the request, a decision shall be taken on the basis of the latest scientific and technical knowledge, after consultation, at the initiative of the Commission or of a Member State, of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers and in accordance with the procedure laid down in Article 10 as to whether the substance in question may be included in a list of permitted substances or whether the national authorization should be revoked. Notwithstanding paragraph 1 (a), the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.

5.2.14 The EU Council Directive on the approximation of the laws of the Member States relating to cosmetic products (EU)

Reference: Directive 2003/15/EC of the European Parliament and the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, (OJ, 11.3.2003).

Organization: Council of the European Communities

Importance of Article: Makes 2003 amendments to the Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.

Key Points and Important Information:

- Clause (12) of the preamble states: “The SCCNFP (Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers) stated in its opinion of 25 September 2001 that substances classified pursuant to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling dangerous substances as carcinogenic (except substances only carcinogenic by inhalation), mutagenic or toxic for reproduction, of category 1 or 2, and substances with similar potential, must nor be intentionally added to cosmetic products, and that substances classified pursuant to Directive 67/548/EEC as similar potential, must not be intentionally added to cosmetic products unless it can be demonstrated that their levels do not pose a threat to the health of the consumer”.
- Carcinogens that are carcinogenic by inhalation and substances that are toxic to reproduction category 1 are discussed in section 5.2.8.
- Clause (13) of the preamble states: “Given the special risks that substances classified as carcinogenic, mutagenic or toxic for reproduction, category 1, 2 and 3, pursuant to Directive 67/548/EEC may entail for human health, their use in cosmetic products should be prohibited. A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products. (Directive, page 2, 2003/15/EC)”
- Article 4b of the Directive states: “The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 10(2). A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products”.

5.2.15 The Council Directive concerning cosmetic products for the purposes of adapting Annexes II and III thereto to technical progress (EU)

Reference: Commission Directive of 21 November 2005, amending Council Directive 76/768/EEC concerning cosmetic products for the purposes of adapting Annexes II and III thereto to technical progress, (2005/80/EC), (OJ L 303, 22.11.2005, pages 0032 – 0037).

Organisation: The Commission of the European Communities.

Importance of Article: - Indicates that since Directive 67/548/EEC has been amended by Directive 2004/73/EC, it is therefore necessary to adopt measures so as to bring Directive 76/768/EEC in line with the provisions of Directive 67/548/EEC.

Key Points and Important Information:

- Directive 76/768/EEC, as amended by Directive 2003/15/EC of the European Parliament and of the Council [2], prohibits the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1, 2 and 3, under Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [3], but allows the use of substances classified in category 3 pursuant to Directive 67/548/EEC subject to evaluation and approval by the Scientific Committee on Cosmetic products and Non-Food Products intended for consumers SCCNFP, replaced by the Scientific Committee on Consumer Products (SCCP) by Commission Decision 2004/210 [4].
- This means that, as given in 2004 by the Scientific Committee on Consumer Products, Category 3 substances are allowed in cosmetic products, despite Annex I of the Council Directive 67/548/EEC Directive prohibiting any carcinogenic, mutagenic or toxic for reproduction (CMR) substance, of category 1, 2 and 3, for use in cosmetics.

- Lead acetate is classified as toxic to reproduction, category 1; R61. “May cause harm to the unborn child”.
- Lead acetate is a category 3 CMR.
- Lead acetate is both a category 1 and category 3 CMR
- The SCCP recommends that this is a category 3 CMR lead compound allowed in cosmetics.

5.2.16 Amendment to the Dangerous Preparations Directive 1999/45/EC (EU)

Reference: Commission Directive 2006/8/EC of 23 January 2006 amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, Official Journal L 019 , 24/01/2006 P. 0012 – 0019

Organisation: The Commission of the European Communities

Importance of Article: This article relates to the classififcation, packaging and labelling of dangerous preparations, incorporating 2006 amendments. Although this Directive does not apply to Cosmetics, again it is being considered because it relates to substances of c/m/r classification.

Key Points and Important Information:

- Article (1) states “Preparations composed of more than one substance being classified in Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [2] as carcinogenic, mutagenic and/or toxic for reproduction must currently be labelled with risk phrases (R-phrases) to indicate both category 1 or 2 and category 3 classification…classified and labelled with the higher category.”

- The labelling for “preparations containing lead”, stated as irrespective of their classification within the meaning of Articles 5, 6, and 7, on the packaging of paints and varnishes containing lead in quantities exceeding 0,15 % (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars: "Contains lead. Should not be used on surfaces liable to be chewed or sucked by children.”
- In the case of packages the contents of which are less than 125 millilitres, the particulars may be as follows: “Warning! Contains lead.”
- The classification “Cosmetics” are included as part of the meaning to which preparations containing lead apply, irrespective of their meaning in Article 5. Cosmetics are not directly mentioned in this Directive, even though they may be considered to be “preparations that contain lead”.
- According to “The Rules Governing Cosmetic Products in the European Union” (1999), “Cosmetic ingredient” also applies to preparations, whether they be of synthetic or natural origin. Thus preparations used in the industry of cosmetic manufacture must abide by the “Dangerous Preparations and Liquids” Directive.

5.2.17 Council Directive on the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances (EU)

Reference: Commission Directive 1999/11/EC adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances. (1999)

Organization: Council of the European Communities

Importance of Article: This article specifies the guidelines that should be applied on the testing and studies of various items including cosmetic products

Key Points and Important Information:

- Good laboratory practice should be applied on the testing of cosmetic products unless specifically exempted by national legislation.
- Good laboratory practice (GPL) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

TRANSPORT (EU)

5.2.18 International Carriage of Dangerous Goods (EU)

Reference: EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR) (2005)

Organisation: United Nations

Importance of Article: From this page it is possible to view and download the full text of the ADR 2003, applicable as from 1 January 2003, containing provisions, classification, packing, and consignment, when transporting dangerous goods internationally.

Key Points and Important Information:

List of Dangerous Goods

- ADR Part 3, Dangerous goods list, special provisions and exemptions related to dangerous goods packed in limited quantities, <http://www.unece.org/trans/danger/publi/adr/adr2003/English/tableA.pdf>

Table of dangerous goods packed in limited quantities, and the details to follow regarding their special provisions and exemptions for transportation.

UN No.	Name and description	Class	Classification Code	Packing Group	Labels	Limited Quantities	Special Provision	Packaging Instructions	Packaging Special Packing Provisions	Mixed Packing Provisions	UN Portable Tanks Instructions	UN Portable Tanks Special Provisions
0129	LEAD AZIDE, WETTED with not less than 20% water, or mixture of alcohol and water, by mass	1	1.1A		1	266	LQ0	P110(b)	PP42	MP20		
0130	LEAD STYPHNATE (LEAD TRINITRORESORCINATE), WETTED with not less than 20% water, or mixture of alcohol and water, by mass	1	1.1A		1	266	LQ0	P110(b)	PP42	MP20		
1469	LEAD NITRATE	5.1	OT2	II	5.1 +6.1		LQ11	P002 IBC08	B4	MP2		

1470	LEAD PERCHLORATE	5.1	OT2	II	5.1 +6.1		LQ11	P002 IBC06		MP2	T4	TP1
1616	LEAD ACETATE	6.1	T5	III	6.1		LQ9	P002 IBC08 LP02 R001	B3	MP10		
1617	LEAD ARSENATES	6.1	T5	III	6.1		LQ18	P002 IBC08	B4	M10		
1618	LEAD ARSENITES	6.1	T5	III	6.1		LQ18	P002 IBC08	B4	M10		
1620	LEAD CYANIDE	6.1	T5	III	6.1		LQ18	P002 IBC08	B4	M10		
1794	LEAD SULPHATE with more than 3% free acid	8	C2	II	8	591	LQ23	P002 IBC08	B4	M10		
1872	Lead Dioxide	5.1	OT2	III	5.1 +6.1		LQ12	P002 IBC08 LP02 R001	B3	MP2		
2291	LEAD COMPOUND, SOLUBLE, N.O.S.	6.1	T5	III	6.1	199 274 535	LQ9	P002 IBC08 LP02	B3	M10		

							R001			
2989	LEAD PHOSPHITE, DIBASIC	4.1	F3	II	4.1	LQ8	P002 IBC08	B4	M11	
2989	LEAD PHOSPHITE, DIBASIC	4.1	F3	II	4.1	LQ9	P002 IBC08 LP02 R001	B3	M11	

ADR Tank		Vehicle	Transport	Special provisions for carriage				Hazard	UN	Name and description
Tank Code	Special Provisions	for tank carriage	category	Packages	Bulk	Loading, unloading and handling	Operation	identification No.	No.	
			0	V2		CV1 CV2 CV3	S1		0129	LEAD AZIDE, WETTED with not less than 20% water, or mixture of alcohol and water, by mass
			0	V2		CV1 CV2 CV3	S1		0130	LEAD STYPHNATE (LEAD TRINITRORESORCINATE), WETTED with not less than 20% water, or mixture of alcohol and water, by mass
SGAN	TU3	AT	2	V11		CV24 CV28		56	1469	LEAD NITRATE

SGAN	TU3	AT	2	V11 V12		CV24 CV28		56	1470	LEAD PERCHLORATE
SGAH L4BH	TU15 TE1 TE15 TE19	AT	2		VV9b	CV13 CV28	S9	60	1616	LEAD ACETATE
SGAH	TU15 TE1 TE15 TE19	AT	2	V11		CV13 CV28	S9 S19	60	1617	LEAD ARSENATES
SGAH	TU15 TE1 TE15 TE19	AT	2	V11		CV13 CV28	S9 S19	60	1618	LEAD ARSENITES
SGAH	TU15 TE1 TE15 TE19	AT	2	V11		CV13 CV28	S9 S19	60	1620	LEAD CYANIDE
SGAN		AT	2	V11	VV9a			80	1794	LEAD SULPHATE with more than 3% free acid
SGAN	TU3	AT	3			CV24 CV28		56	1872	Lead Dioxide
SGAH L4BH	TU15 TE1 TE15 TE19	AT	2		VV9b	CV13 CV28	S9	60	2291	LEAD COMPOUND, SOLUBLE, N.O.S.
SGAN		AT	2	V11				40	2989	LEAD PHOSPHITE, DIBASIC
SGAH		AT	3		VV1			40	2989	LEAD PHOSPHITE, DIBASIC

ADR Part 3

Reference: Dangerous Goods List and Limited Quantities Exceptions,

Scope and General Provisions (Chapter 3.1)

http://www.unece.org/trans/danger/publi/unrec/rev14/English/03E_Part3.pdf

- When commercial substances that are being transported do not appear specifically on the Dangerous Goods List, their dangerous properties must be identified, and labelled accordingly to the table. (3.1.1.2)

- After determining its dangerous properties, the "generic" or "not otherwise specified" entries shall be classified according to the class definitions and test criteria and the name in the Dangerous Goods List which most appropriately describes the substance or article. (3.1.1.2)

- The classification shall be made by the appropriate competent authority or consignor. (3.1.1.2)

- Once classified, dispatch and transport procedures follow according to the regulations outlined in this article. (3.1.1.2)

(More summarisation):

- not more than the two constituents which most predominantly contribute to the hazard or hazards of a mixture need to be shown, When a mixture of dangerous goods is described by one of the "N.O.S." or "generic" entries

  to which special provision 274 has been allocated in the Dangerous Goods List. This excludes controlled substances when their disclosure is prohibited by national law or international convention. (3.1.2.8.1.2)

- When mixture package is labeled with any subsidiary risk label, one of the two technical names shown in brackets shall be the name of the constituent which gives the subsidiary risk label. (3.1.2.8.1.2)
- “UN No.” refers to the serial number assigned to the article or substance under the United Nations system. (3.2.1)
- “Name and description” refers to the proper shipping names in uppercase characters, which may be followed by additional descriptive text presented in lowercase characters. Some terms explanations appears in Appendix B. Where isomers of similar classification exist proper shipping names may be shown in the plural . “Solution” in a proper shipping name means one or more named dangerous goods dissolved in a liquid that is not otherwise subject to these Regulations. (3.2.1)
- “Class or division” refers to the class or division. In the case of Class 1, the compatibility group assigned to the article or substance according to the classification system is described in Chapter 2.1. (3.2.1)
- “Subsidiary risk” refers to the class or division number of any important subsidiary risks which have been identified by applying the classification system described in Part 2. (3.2.1) (The term “Subsidiary Risk” does not appear in the “Dangerous Goods List”, ADR Part 3, Dangerous goods list, special provisions and exemptions related to dangerous goods packed in limited quantities. The term appears throughout the ADR document in other tables.)
- “UN packing group” refers to the UN packing group number (i.e. I, II or III) assigned to the article or substance. The substance or formulation packing group to be transported shall, based on its properties, be determined through application of the hazard grouping criteria provided in Part 2 (in the case that one packing group is indicated for the entry). (3.2.1)
- “Special provisions” is a number referring to any special provision(s) indicated in 3.3.1 (3.2.1)
- “Limited quantities” provides the maximum quantity per inner packaging or

article authorized for transport of the substance. This is according to the provisions for limited quantities in Chapter 3.4. (3.2.1)

- "Packing instruction" contains alpha numeric codes referring to the relevant packing instructions in section 4.1.4. These indicate the packaging (including IBCs and large packagings), which may be used for the transport of substances and articles.A code including the letter "P" refers to packing instructions for the use of packagings that are described in Chapters 6.1, 6.2 or 6.3. "IBC" refers to packing instructions for the use of IBCs (intermediate Bulk Containers) that is described in Chapter 6.5.
- A code of the letters "LP" refers to packing instructions for the use of large packagings described in Chapter 6.6.
- When code not provided, substance is not authorized in the type of packaging that may be used according to the packing instructions bearing that code.
- N/A means that the substance or article need not be packaged.

ADR Part 2

Reference: Classification
http://www.unece.org/trans/danger/publi/unrec/rev14/English/02E_Part2.pdf

Importance of Article: Establishes the meaning of the codes of classification assigned certain substances that are transported universally.

Key Points and Important Information:

Classification Code:

Class 1: Explosives
Division 1.1: Substances and articles which have a mass explosion hazard
Division 1.2: Substances and articles which have a projection hazard but not a mass explosion hazard
Division 1.3: Substances and articles which have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but

not a mass explosion hazard
Division 1.4: Substances and articles which present no significant hazard
Division 1.5: Very insensitive substances which have a mass explosion hazard
Division 1.6: Extremely insensitive articles which do not have a mass explosion hazard
Class 2: Gases

Division 2.1: Flammable gases
Division 2.2: Non-flammable, non-toxic gases
Division 2.3: Toxic gases

Class 3: Flammable liquids

Class 4: Flammable solids; substances liable to spontaneous combustion; substances which, on contact with water, emit flammable gases
Division 4.1: Flammable solids, self-reactive substances and solid desensitized explosives
Division 4.2: Substances liable to spontaneous combustion
Division 4.3: Substances which in contact with water emit flammable gases

Class 5: Oxidizing substances and organic peroxides
Division 5.1: Oxidizing substances
Division 5.2: Organic peroxides

Class 6: Toxic and infectious substances
Division 6.1: Toxic substances
Division 6.2: Infectious substances

Class 7: Radioactive material

Class 8: Corrosive substances

Class 9: Miscellaneous dangerous substances and articles

- Note: The numerical order of the classes and divisions does not indicate the degree of danger. Also, many of the substances assigned to Classes 1 to 9 are deemed environmentally hazardous. This does not require further labeling. (2.0.1.2)

- Substances other than Classes 1, 2 and 7, divisions 5.2 and 6.2
  and other than self-reactive substances of Division 4.1 are assigned to three packing groups:
  Packing group I: Substances presenting high danger;
  Packing group II: Substances presenting medium danger; and
  Packing group III: Substances presenting low danger.

5.2.19 Security of the Carriage of Dangerous Goods (EU)
Reference: Security of the Carriage of Dangerous Goods (2003)

Organisation: United Nations Economic Commission for Europe

Importance of Article: Joint Meeting of the RID Safety Committee and the Working Party on the Transport of Dangerous Goods

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), of 30 September 1957

others

Protocol amending article 1 (a), article 14 (1) and article 14 (3) (b) of the European Agreement of 30 September 1957 concerning the International Carriage of Dangerous Goods by Road (ADR), of 28 October 1993

Convention on Civil Liability for Damage caused during Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels (CRTD), of 10 October 1989

European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN), of 25 May 2000

5.2.20 European Agreement Concerning The International Carriage of Dangerous Goods by Inland Waterways (EU)

Reference: European Agreement Concerning The International Carriage of Dangerous Goods by Inland Waterways (AND) (2001)

Organisation: United Nations

Importance of Article: Outlines safety of international carriage of dangerous goods by inland waterways; contributing effectively to the protection of the environment, by preventing any pollution resulting from accidents or incidents during such carriage; and facilitating transport operations and promoting international trade.

5.2.21 International Standards

Reference: Cosmetics -- Packaging and Labelling

Organisation: **International Organisation for Standardisation**

Key points and Important Information:

- ISO 22715:2006 specifies requirements for packaging and labelling of all cosmetic products as defined according to national regulations or practices intended for sale or free distribution. The standard can be purchased for CHF 48,00 (Swiss Franc).

5.2.22 RISK COMMITTEES AND RISK ASSESSMENT TESTS

The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers

Reference: Proposal for Recommended Mutagenicity / Genotoxicity Tests for the Safety Testing of Cosmetic Ingredients to be Included in the Annexes to Council Directive 76/768/EEC. (2003).

Organisation: SCNNFP

Importance of Article: Outlines necessity to address potential affects of mutagenicity and genotoxicity through risk assessments. Mutagenic chemicals may present a hazard to health since exposure to a mutagen carries the risk of inducing germ-line mutations, with possibilities of inherited disorders, and the risk of somatic mutations including those leading to cancer.

Key Points and Important Information:

- The term Mutagenicity refers to the induction of permanent transmissible changes in the amount or structure of the genetic material of cells or organisms.
- These changes involve a single gene or gene segment, a block of genes, or whole chromosomes. Effects on whole chromosomes may be structural and/or numerical.
- Genotoxicity: refers to potentially harmful effects on genetic material, which are not necessarily associated with mutagenicity.
- Tests for genotoxicity include tests which provide an indication of induced damage to DNA (but not direct evidence of mutation) via effects such as unscheduled DNA synthesis (UDS), sister chromatid exchange (SCE), DNA strandbreaks, DNA adduct formation or mitotic recombination, as well as tests for mutagenicity.
- Mutation involves a permanent change in the amount or structure of the genetic material of an organism, which may result in a heritable change in organism characteristics.

- Mutation alterations may involve individual genes, blocks of genes, or whole chromosomes. Mutations involving single genes may be a consequence of effects on single DNA bases (point mutations) or of larger changes, including deletions and rearrangements of DNA.
- Changes in chromosomes as entities may be numerical or structural.
- A mutation in the germ cells of sexually reproducing organisms may be transmitted to the offspring.
- A mutation that occurs in somatic cells may be transferred only to descendent daughter cells.

Aneuploidy:

- a type of mutation from malsegregation, as the segregation of chromosomes during both mitotic and meiotic cell division are modified by chemicals.
- Observed effects: involves a change in chromosome number from the normal diploid or haploid status of a species, whereas polyploidy represents an increase in chromosome number which is an exact multiple of the haploid number, e.g. triploidy (3n) and tetraploidy (4n).
- Health risks: Aneuploidy makes a major contribution to human embryonic loss and some birth defects such as Down Syndrome (trisomy of chromosome 21).
- Chemicals are termed anegens when they induce aneuploidy as their predominant mutagenic effect. A wide range of chemicals (primarily those which modify the spindle of the dividing cell) such as colchicine, benomyl, trichlorphon and griseofulvin have been shown to induce aneupoloidy in test systems ranging from *in vitro* cultured mammalian cells and somatic tissue of intact animals, to germ cells of rodents.
- Currently, evidence for the carcinogenicity of aneugens is limited. However, a large number of aneugens are inducers of malignant transformation in Syrian hamster cells *in vitro*.
- the Committee concludes that the testing of chemicals for potential aneugenic activity should be included in genotoxicity testing.

- This is by being given the association between aneuploidy and heritable effects in germ cells, and potential carcinogenicity.
- These three levels of mutation- namely gene, clastogenicity (i.e. structural chromosome aberrations) and aneuploidy (i.e. numerical chromosomal aberrations)- are provided comprehensive coverage of the mutagenic potential of a chemical, also when assessing carcinogenic potential, since all three types of mutation have been shown to be associated with the activation and expression of oncogenes, and loss or inactivation of tumour suppressor genes and other classes of genes implicated in carcinogenesis.
- Genotoxic (or genotoxicity) refers to agents which interact with the DNA and/or the cellular apparatus which regulates the fidelity of the genome, e.g. the spindle apparatus, and enzymes such as the topoisomerases.
- Genotoxic is a broad term that includes mutation as well as damage to DNA or the production of DNA adducts, by the chemical itself or its metabolites.
- Genotoxic effects also include unscheduled DNA synthesis (UDS), sister chromatid exchange (SCE) and mitotic recombination.
- The detection of such effects in itself does not provide direct evidence of inherited mutations.
- There is currently no single validated test that can provide information on all three end-points, namely gene mutation, clastogenicity and aneuploidy.
- Thus the Committee states it is necessary to subject a given substance to several different assays.

Stage 1 Tests:

- 1. Bacterial Test for gene mutation
- 2. Test for clastogenicity and for indication of aneugenicity *i) in vitro* metaphase analysis or *ii) in vitro* micronucleus test
- 3. Mammalian cell mutation assay (currently, the preferred choice in the mouse lymphoma assay)

- Test 3 is not required for those substances where there will be little or no human exposure

MUTAGENICITY TESTING REQUIREMENTS IN DIFFERENT SECTORS

BIOCIDES

- The biocidal product shall pose only a low risk to humans, animals and the environment.
- The common core data set for active substances considered by this Directive requires, among the toxicological and Metabolic studies (6.6. of Annex IIA):
    1. *In vitro* gene mutation study in bacteria
    2. *In vitro* cytogenicity study in mammalian cells
    3. *In vitro* gene mutation assay in mammalian cells
    4. If positive in 1, 2 3, then an *in vivo* mutagenicity study will be required (bone marrow assay for chromosomal damage or a micronucleus test)
    5. If negative in 6.6.4 but positive *in vitro* tests then undertake a second *in-vivo* study to examine whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow
    6. If positive in 4 then a test to assess possible germ cell effects may be required

FOOD ADDITIVES

- The EU Scientific Committee on Food recommends a battery of four tests should be used: two at gene level (in prokaryotic and eukaryotic cells) and two at the chromosome level (*in vitro* and *in vivo*) (see Table 1).
- EC Scientific Committee on Food Measurements of:
    1. a test for induction of gene mutations in bacteria
    2. a test for induction of chromosome aberrations in mammalian cells *in vitro*
    3. a test for induction of gene mutations in mammalian cells *in vitro*

4. positive results in any of the above *in vitro* test will normally require further assessment of genotoxicity *in vivo.*

COSMETICS

- The safety evaluation Procedure as applied by the SCCNFP refers to the ingredients in Annexes III, IV, VI and VII of Directive 76/768/EEC, as stated on page 14 of SCC "Notes of Guidance for Testing of Cosmetic Ingredients for Their Safety Evaluation".
- Annex III is a list of substances which cosmetic products must not contain except subject to restrictions and conditions laid down;
  Annex IV is a list of colouring agents allowed for use in cosmetic products;
  Annex VI is a list of preservatives which cosmetic products may contain;
  Annex VII is a list of UV filters which cosmetic products may contain.
- All these ingredients, for their chemical properties, might present a risk to human health, and they therefore require an adequate design of toxicological studies, including the mutagenicity studies.

SPECIFIC CONSIDERATIONS ABOUT THE TESTS

1. LIMITED EFFECTIVENESS OF BACTERIAL TESTS

- There are circumstances where the performance of the bacterial reverse mutation test does not provide sufficient information for the assessment of genotoxicity.
- This may be the case for compounds that are highly toxic to bacteria (e.g., some antibiotics) and compounds thought or known to interfere with mammalian cell-specific systems (e.g., topoisomerase inhibitors, nucleoside analogues, or certain inhibitors of DNA metabolism).

- In these cases, usually two *in vitro* mammalian cell tests should be performed using two different cell types and two different endpoints, i.e., gene mutation and chromosomal damage.
- Test approaches currently accepted for the assessment of mammalian cell gene mutation include tests for mutation: 1) at the tk locus using mouse lymphoma L5178Y cells or human lymphoblastoid TK6 cells; 2) at the hprt locus using CHO cells, V79 cells, or L5178Y cells; or 3) at the gpt locus using AS52 cells.
- it is still important to perform the bacterial reverse mutation test when these additional tests are performed. This is because of the high level of toxicity of the test chemical to bacteria, since some antibacterial agents, albeit highly toxic to the tester strains, are genotoxic at very low, sub-lethal concentrations in the bacterial reverse mutation test (e.g., nitrofuran antibiotic).

2. LIMITED SENSITIVITY OF TWO ASSAYS

- Combination of assays for gene mutation in bacteria and for chromosomal aberrations (plus aneuploidy) in mammalian cells may not detect a small proportion of agents with the potential for *in vitro* mutagenicity.
- A third assay, comprising an additional gene mutation assay in mammalian cells, should be used, except for compounds for which there is little or no human exposure.
- Certain mammalian cell gene mutation protocols that have been widely employed, particularly some of those involving the use of Chinese hamster cells, are now considered to be insufficiently sensitive, predominantly on statistical grounds.
- Measuring mutations at the thymidine kinase (tk) locus in L5178Y mouse lymphoma cells has gained broad acceptance. This has the advantage of detecting not only gene mutations but also various sizes of chromosome deletions.

3. THE NEED TO INCLUDE THE *IN VITRO* MICRONUCLEUS TEST

- Possible permanent changes in DNA sequence may come about from the genome sustaining a wide spectrum of damage.
- The DNA lesions induced by chemical mutagens need the cell to pass through the cell cycle before being expressed as cytological endpoints.
- Mechanisms involved in the control and regulation of cell cycle may be altered by the presence of DNA damages, leading to different cellular responses in relation to the nature and/or the number of lesions.
- The expression of molecular damages is complex and may be expressed under different cytological levels.
- Structural chromosomal aberrations (CA) result from breakages and/or breakage – rejoining events that occur during the G0/G1 or G2 stages of the cell cycle. However, these are visualized when cells are at the metaphase stage.
- Micronuclei (MN) arise during cell division from either chromosome laggards in anaphase or from chromosome fragments. Therefore, micronuclei may contain a whole chromosome and/or an acentric fragment.
- The cytokinesis block assay based on the inhibition of actins in the division furrow by cytochalasin-B allows the identification of cells having divided once in culture.
- Moreover it is possible to distinguish between stable chromosome rearragements, chromosome loss, chromosome breaks and chromosome nondisjunction by combining both assays with fluorescence in situ hybridisation (FISH) using pancentromeric or chromosome specific probes.
- Using these cytogenetic methodologies together will enable reaching higher sensitivity for the adequate and refined hazard assessment of mutagens and will lead to a better understanding of the biological mechanisms involved.

SCCNFP OPINION: NOTES OF GUIDANCE

MUTAGENICITY/GENOTOXICITY

- It is necessary in the Cosmetic Safety Evaluation to address the potential effect of "mutagenicity/genotoxicity"; somatic cell mutagens are considered, moreover, to be involved in neoplastic transformations.
- Mutagenicity refers to inducting permanent transmissible changes in the amount or structure of the genetic material of cells or organisms. Changes may involve a single gene or gene segment, a block of genes or whole chromosomes.
- Effects on whole chromosomes may be structural and/or numerical.
- Genotoxicity is a broader term and refers to potentially harmful effects on genetic material which are not necessarily associated with mutagenicity. Thus, tests for genotoxicity include tests which provide an indication of induced damage to DNA (but not direct evidence of mutation) via effects such as unscheduled DNA synthesis (UDS), sister chromatid exchange (SCE), DNA strandbreaks, DNA adduct formation or mitotic recombination, as well as tests for mutagenicity.
- At present, no single validated test method can provide information on all the above mentioned genetic endpoints; their diversity usually precludes the detection of more than one of them in a single system.
- Several *in vitro* and *in vivo* mutagenicity/genotoxicity tests are available : described in OECD Guidelines, and Annex V to Directive 67/548/EEC (13).
- The SCCNFP is of the opinion that the base level of evaluation of the potential for mutagenicity/genotoxicity of a cosmetic ingredient that is to be included in Annexes III,IV,VI and VII of Council Directive 76/768/EEC should include tests to provide information on the three major genetic endpoints, namely (1) mutagenicity at a gene level, (2) chromosome breakage and/or rearrangements (clastogenicity),and (3) numerical chromosome aberrations (aneugenicity).
- These three base level of information represent the actual consensus of international groups of scientific experts,and of an expert advisory committee.
- By considering that the Bacterial Reverse Mutation Test in the Salmonella assay does not detect all compounds with mutagenic potential, the SCNNFP recommends that an additional gene mutation assay in mammalian cells is necessary for the evaluation of those chemicals like the cosmetic ingredients to

which a large fraction of the consumers, because a great part of their lifetime is exposed.

- The need to include two test for detection of gene mutations is recognized also for the evaluation of food additives and biocides.

RECOMMENDATIONS

STAGE 1 : *IN VITRO* TESTS

1. Tests for gene mutation

1.1. Bacterial Reverse Mutation Test (OECD 471, 21st July 1997; EC B.13/14, 19th May 2000)

1.2. *In vitro* Mammalian Cell Gene Mutation Test (currently, the preferred choice is the mouse lymphoma assay) (OECD 476 21st July 1997; EC B.17, 19th May 2000)

2. Tests for clastogenicity

2.1. *In vitro* Mammalian Chromosome Aberration Test (OECD 473, 21st July 1977; EC B.10 19th May 2000)

3. Tests for aneugenicity and non-disjunction

3.1. In Vitro Micronucleus Test (Guideline proposed to OECD) (18)

- In instances for which the base level of all four in vitro tests seems not necessary or should be modified, a scientific justification for deviation from the battery of tests, and the decision taken should be given.
- The article also states that certain structurally alerting molecular entities are recognised as being casually related to the carcinogenic and/or mutagenic potential of chemicals, whereby examples of structural alerts include: alkylating electrophilic centers, unstable epoxides, aromatic amines, azostructures, N-nitrosogroups, aromatic nitro-groups.
- It is also established that specific protocol modifications/additional tests are necessary for optimum detection of genotoxicity for some classes of compounds with specific structural alerts. Such modifications could consist of the additional testing needed when the chosen four-test battery yields negative results for a structurally alerting test compound.

In Vitro Metabolic Activation

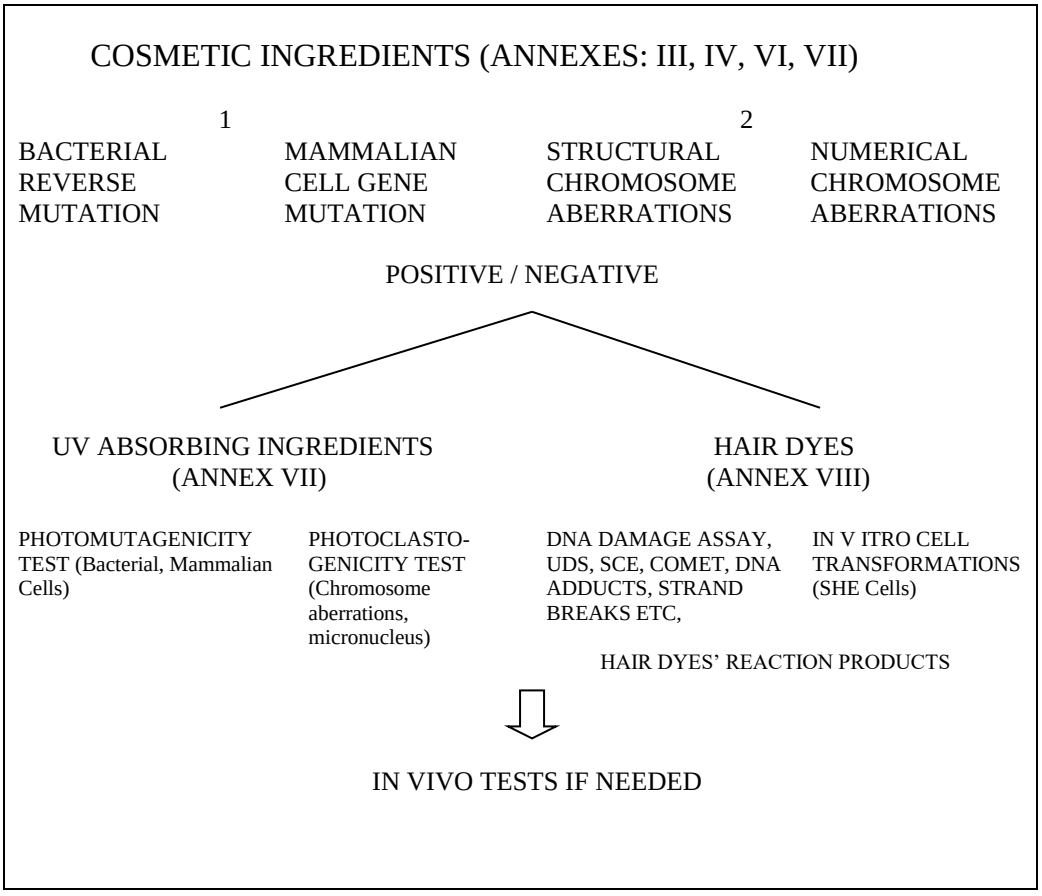
- Cells should be exposed to the test substance both in the presence and absence of an appropriate metabolic activation system, the most commonly used system being a cofactor-supplemented postmitochondrial fraction (S9) prepared from the livers of rodents (usually rat) treated with enymeinducing agents (such as Aroclor 1254) or a combination of phenobarbitone and betanaphthoflavone.
- The post-mitochondrial supernatant fraction is usually used at concentrations in the range from 10 to 30 percent v/v in the S9 mix.
- It may depend upon the class of chemical being tested regarding choice and concentration of metabolic activation system may. In some cases it may be appropriate to utilize more than one concentration of post-mitochondrial fraction.
- For azo dyes and diazo compounds a reductive metabolic activation system is appropriate

In vivo studies

- When some concern is raised by positive results from *in vitro* tests, it may be justifiable to perform further testing.
- The selection of the *in vivo* assays cannot be defined a priori, and it depends on the positive results observed in the *in vitro* assays.
- Before undertaking any *in vivo* testing, a thorough review is needed of the *in vitro* test results of the substance with toxicokinetic profile, which is available information on its chemistry and toxicological profile, as well as data on analogous ingredients.
- A particular *in vivo* test should be conducted only when it can be reasonably expected that the specific target tissue will be adequately exposed to the test substances and/or its metabolites from all the properties of the test substance and the proposed test protocol.

- Testing oxidative hair dye ingredients for their potential genotoxicity/mutagenicity/carcinogenicity is a new strategy imposing six *in vitro* tests instead of the four mentioned above.
- This views the fact that several permanent hair dyes formulations contain aromatic amines, or else forms them during the oxidative reaction.
- The *in vitro* level 1 of genotoxicity/mutagenicity testing strategy recommended by the SCCNFP for different classes of cosmetic ingredients to be included in the technical annexes of Directive 76/768/EEC are as follows:

IN VITRO MUTAGENICITY / GENOTOXICITY TESTING STRATEGY RECOMMENDED BY SCCNFP (An illustrative copy of the steps are reproduced in full below as they appear in the SCCNFP table. Notes of Guidance (SCCNFP/0690/03**)).**



5.2.23 IMPLEMENTATION OF TESTS – For Lead in Cosmetics

Reference: Adamson Analytical Laboratories Inc. (2006).

Importance of Article: An example of a laboratory that tests for the presence of lead products, including cosmetics, by using various technologies.

Key Points and Important Information:

- Sunscreen-Suntan Products Testing:
  AAL, Inc. performs complete chemical testing on raw material and the finished product of sunscreen samples.

  Procedure:

  The raw material analysis of sunscreen ingredients includes active and etcipient chemicals. Ingredients are analysed according to USP monograph. Identification is done by:

  - FTIR fingerprint

  - Ultra-violet

  -Visible Spectrometry Scans

  -Limit Test

  Impurities located are:

  - lead

  - Mercury

  -Arsenics

  The Purity and Assay tests can also be completed by gas chromatography (GC) and high performance liquid chromatography (HPLC).

  The finished products of over-the-counter sunscreen (i.e. SPF-4 to SPF-30+) active content analysis are performed by high performance liquid chromatography

(HPLC). Validated testing procedures for sunscreen analysis of active chemicals for up to seven actives.

- Preservative and Additive Analysis

  AAL's cosmetics scientists can analyze most of the additives ingredients they have listed on their site by USP monograph and FDA Cosmetics Handbook techniques. Computerized automated HPLC and GC perform all chemical testing. Chemical analysis conducted under GMP requirements and complies with USP Chromatography system suitability requirements. Color Additives analyzed by Chromatographic HPLC and TLC Instrumentation.

- Antioxidants:

  Analysis

  AAL's cosmetic lab has validated methods, such as computerized automated HPLC, for analysis of most of the antioxidant ingredients. AAL also has methods that analyze trace contents of antioxidants for cleaning validation study.

- Skin Therapeutic Products

  AAL analyzes chemicals that function to improve the skin, including acne creams, astringents, pore cleaners, anti pimple agents, anti-rash creams, and antibacterial lotions. They specialise in skin therapeutic products sold as over-the-counter.

  Analysis

  AAL's cosmetic lab has validated methods for analysis of the active compounds of skin therapeutic products. The chromatographic methods for assay are utilized for automated HPLC and HPGC.

- Antidandruff Shampoo

Offers a clinical viewpoint of the product: “Dandruff is due to small scales of dead skin forming on the scalp, and is a variation of the normal process of scalp growth and regeneration. It is also associated with scalp overgrowth by Malassezia Furfur yeast, and thought to be a mild form of seborrhoeic dermatitis.”

Analysis

The active chemicals of raw material and finished products are analyzed by instrumentation such as HPLC, GC, and USP monograph.

Partial List of the chemicals commonly used:

Clotrimazole; Test Method used: HPLC

Coal Tar HPLC

Ketoconazole HPLC

Menthol GC

Salicylic Acid HPLC

Selenium Sulfide Titration

Zinc Pyrithion Titration/HPLC

- Antiperspirant/Deodorant

  The antiperspirant active ingredients are analyzed according to USP method.

- Dental Care Products Testing

  The laboratory analyses dental care products such as oral rinses, oral gel, dental bleach, anti-cavity toothpastes, and mouth sprays. Test Methods include HPLC, GC, Titration, ISE

- OTC Antibacterial Antibiotic/Hygiene Care

  Test Methods include HPLC, GC, Titration

5.2.24 IMPLEMENTATION OF TESTS- For determining the Risk of Lead

Recommended Test Procedures

Reference: The value of alternative testing for neurotoxicity in the context of regulatory needs. (2005).

Organisation: European Centre for the Validation of Alternative Methods (ECVAM), Institute for Health & Consumer Protection, European Commission Joint Research Centre, Ispra (VA), Italy

Importance of Article:

Key Points and Important Information:

- Any modification to the structure and/or function of the nervous system, i.e. the brain, spinal cord, body function controlling nerves, following exposure to a chemical, biological or physical agent, may be considered as a neurotoxic insult.
- Functional changes may result from neurotoxic insults like industrial chemicals, cosmetic ingredients, pharmaceuticals, foods, food additives and naturally occurring substances.
- Prediction of neurotoxicity is a key feature in the toxicological profile of compounds, and so testing them is required by many regulatory testing schemes. Risk assessment takes into account the probability of a substance to cause damage under relevant use conditions including, dose–response studies and also the assessment of exposures to compound mixtures.

United Kingdom

5.2.25 Cosmetic Products Safety Regulations (UK)

Reference: Statutory Instrument 2004 No. 2152 The Cosmetic Products (Safety) Regulations 2004. Schedule 4, Part 1, Reference No 55. Published by Queen's Printer of Acts of Parliament.

Organisation: Secretary of State (United Kingdom)

Importance of Article: This article lists lead and lead compounds as prohibited substances in cosmetics except lead acetate which may be present on certain restriction only for hair dyeing.

Key Points and Important Information:

- Lead and its compounds (except lead acetate subject to the restrictions laid down in entry number 55 in Part I of Schedule 4) are listed as Substances Prohibited in All Cosmetics Products in Schedule 3 Part I
- Lead acetate is listed as a substance which cosmetic product must not contain except subject to restriction in Schedule 4
- Lead acetate can be present up to 0.6% only in hair dyeing and the use on eyelashes, eyebrows or moustaches are prohibited.

5.2.26 Cosmetic Regulations in UK (UK)

Reference: Volume 14: Responsibilities for Human and Animal Health Section 7. Human and veterinary medicines and cosmetics (2000)

Organisation: The BSE Inquiry

Importance of Article: This article states that UK cosmetic regulation is based on the European Union cosmetic regulation (1976).

Key Points and Important Information:

- Section 7.111 states: ‘The regulation of cosmetics was based on the EU Cosmetics Directive (1976), which was implemented in the UK by Regulations made under the Consumer Protection Act 1987. Cosmetic products were required

to meet various safety requirements but, unlike medicinal products, they did not require a licence.'

- Section 7.116 states that substances included in Annex II of the Directive are prohibited in marketing. According to Section 5.2.7 of this report lead and its compounds are included in Annex II

Canada

5.2.27 Advisory - Traditional Kohl Products Contain Lead (Canada)

Reference: Advisory - Traditional kohl products contain lead, 28th September 2005.

Organization: Health Canada (2005a)

Importance of Article: This health advisory acknowledges the fact that dangerous cosmetic products such as leaded kohl can be on the market and cause elevated blood lead levels in children despite Canadian regulations which ban such products.

Key Points and Important Information:

- Kohl (also known as: kajal, surma, al-kahl/al-kohl) is a traditional eye cosmetic of Middle Eastern, Asian and North African societies that is also at times used medicinally as a natural health product.
- Several children in Canada exposed to kohl containing lead have been identified with elevated levels of lead in their blood, putting them at risk of serious health problems.
- Traditional Kohl Products Contravene Canada's Food and Drugs Act.
- As a natural health product, kohl has many uses that vary among cultures, including: use as an aid in the healing of the infant umbilical cord stump, circumcision after-care, eye infection protection, blood clotting aid, digestive aid, sunglare prevention/eyestrain reliever, and general anti-microbial treatment. To be

sold in Canada, the *Natural Health Products Regulations* require natural health products to have a valid market authorization in the form of an eight digit number proceeded by acronym NPN or DIN-HM. Natural health products without this on the label have not been reviewed and approved for safety and efficacy by Health Canada. To date, Health Canada has not received any kohl product submissions for approval, and no kohl product is approved as a natural health product in Canada.

- Similarly, for any cosmetic product to be sold in Canada, Health Canada must be notified of the product's ingredients, to ensure they comply with the regulations. Lead is forbidden and therefore any kohl product containing lead would be too. To date, Health Canada has not been notified of any traditional kohl product.
- Health Canada is taking action to remove lead-containing kohl from the market and to prevent further importation into Canada by working with retailers, importers and the Canada Border Services Agency.

5.2.28 May 2005 Changes to List of Prohibited and Restricted Cosmetic Ingredients (Canada)

Reference: List of Prohibited and Restricted Cosmetic Ingredients (the Cosmetic Ingredient "Hotlist") May 2005 changes to the Cosmetic Ingredient "Hotlist".

Organisation: Health Canada (2005b)

Importance of Article: The changes made in May 2005 to Canada’s Cosmetic Ingredient "Hotlist", include the highly significant world-first ban on lead acetate in cosmetics.

Key Points and Important Information:

- The May 2005 changes to the Cosmetic Ingredient "Hotlist" includes among Items Amended: “**Lead acetate** (301-04-2). This ingredient is no longer restricted but

prohibited for use in cosmetic products based on data indicating skin absorption and possible links to carcinogenicity and reproductive toxicity."

5.2.29 Food and Drugs Act (Canada)

Reference: Food and Drugs Act. Act current to September 27, 2005.

Organisation: Health Canada (2005c)

Importance of Article: This Act controls ingredients, packaging, sale or conditions of sale and labelling of food, drugs and therapeutic devices, as well as cosmetics in Canada.

Key Points and Important Information:

- The Act defines "cosmetic" as including any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes
- Clause 16 of the Food and Drug Act states: "No person shall sell any cosmetic that: (*a*) has in or on it any substance that may cause injury to the health of the user when the cosmetic is used,

  (i) according to the directions on the label or accompanying the cosmetic, or

  (ii) for such purposes and by such methods of use as are customary or usual therefore
- The Minister for Health may designate Inspectors who have the power to inspect premises where any article covered by the act may be manufactured or stored, and to seize and detain the article.

5.2.30 Food and Drugs Act – Cosmetic Regulations (Canada)

Reference: Food and Drugs Act – Cosmetic Regulations, Updated to August 31, 2004 .

Organisation: Health Canada (2004)

Importance of Article: The Cosmetic Regulations control ingredients, packaging, sale or conditions of sale and labelling of cosmetics manufactured in Canada as well as cosmetics imported into Canada.

Key Points and Important Information:

- IMPORTATION INTO CANADA

5. Subject to section 9, no person shall import into Canada for sale a cosmetic the sale of which in Canada would constitute a violation of the Act or these Regulations.

6. An inspector may examine and take samples of any cosmetic sought to be imported into Canada.

7. Where an inspector examines or takes a sample of a cosmetic pursuant to section 6, he may submit the cosmetic or sample to an analyst for analysis or examination.

8. Where an inspector, on examination of a cosmetic or sample thereof or on receipt of a report of an analyst of the result of an analysis or examination of the cosmetic or sample, is of the opinion that the sale of the cosmetic in Canada would constitute a violation of the Act or these Regulations, the inspector shall so notify in writing the collector of customs concerned and the importer.

9. (1) Where a person seeks to import a cosmetic into Canada for sale and the sale would constitute a violation of the Act or these Regulations, that person may, if the sale of the cosmetic would be lawful in Canada after relabelling or modification of the cosmetic, import the cosmetic into Canada on condition that

(*a*) he gives to an inspector notice of the proposed importation; and

(*b*) the cosmetic will be relabelled or modified under the supervision of an inspector in such a manner as to enable the sale of the cosmetic to be lawful in Canada.

(2) No person shall sell a cosmetic that has been imported into Canada pursuant to subsection (1) unless the cosmetic has been relabelled or modified to the satisfaction of the inspector under whose supervision the relabelling or modification was carried out within three months after the importation of the cosmetic into Canada or within such longer period as the Assistant Deputy Minister may specify.

10. No person shall import a cosmetic into Canada for sale unless the information and materials required by section 30 have been filed with the Assistant Deputy Minister in respect of that cosmetic.

New Zealand

5.2.31 Cosmetic Regulations (NZ)

Reference: Review of the regulation of products at the interface between cosmetics and therapeutic goods (2005)

Organisation: Therapeutic Goods Administration Department of Health and Ageing Australian Government

Importance of Article: This article states New Zealand does not have any regulation that is specifically assigned for cosmetics

Key Points and Important Information:

- In section 2.2 it is stated that “there is no New Zealand Act or regulations dedicated solely to cosmetics”.

- The following **warning** must be displayed, “Contains lead acetate. Keep away from children. Avoid all contact with the eyes. Wash hands after use. Do not use to dye eyelashes, eyebrows or moustaches. If irritation develops discontinue use.”

5.2.32. List of Prohibited Ingredients in Cosmetics

Reference: Schedule 3 Components Cosmetic Products Must Not Contain (2006)

Organization: Environmental Risk Management Authority (ERMA)

Importance of Article: Lead and its compounds are prohibited as cosmetic ingredients

Key Points and Important Information:

- In this article “lead and its compounds” (No. 289 Table 2) is included as Components Cosmetic Products Must Not Contain

Singapore

5.2.33 Cosmetic Regulations (SG)

Reference: SINGAPORE Based on information collected up to July 2003 (2003)

Organisation: United Nations Conference on Trade and Development (UNCTAD)

Importance of Article: This article states that cosmetic must be free of lead and its compound.

Key Points and Important Information:

- In Section 81.5 it is stated that “Cosmetics must be free from lead or its compounds”

- For the major part of goods, Singapore's technical regulations are in conformity with the Trader's Manual for ASIA and the Pacific, Singapore, 1988 published in Economic and Social Commission for Asia and the Pacific (ESCAP) and Government Gazette, No. 45 of 23 September 1988 respectively.
- National standards in Singapore are promulgated by SPRING Singapore, known as Singapore Productivity Standards and Innovation for Growth Board. Items such as electrical, electronic, gas appliances, sanitary and building products are subject to standards in place.

5.2.34 Cosmetic Regulations (SG)

Reference: GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS (2006)

Organisation: Health Science Authority (HAS)

Importance of Article: This article includes lead and its compounds as restricted substances in cosmetic products.

Key Points and Important Information:

- In the table 'RESTRICTED SUBSTANCES IN COSMETIC PRODUCTS' [page 10] it is listed that lead and its compounds may be present in cosmetic products at a concentration not exceeding 20 parts per million (by weight) calculated in lead
- Cosmetic products are defined as products intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and includes a deodorant or any depilatory substance but does not include a soap. The cosmetic products are divided into 2 categories.
- The category I products require a license prior to their manufacture, import, sale or supply. These includes:

    - Cosmetic products for application on the region around the eye, including eye creams, eye shadows, eyeliners and mascaras.
    - Cosmetic products for application on the lips, including lipsticks, lip colours and lip creams.
    - Oral or dental hygiene products, including mouth refreshers and dentifrices.
    - Hair dyes containing phenylene diamines; their N-substituted derivatives and their salts; diaminophenols.
- The category II products do not require a license for importation, sale or supply. These comprise cosmetic products for application on the hair, scalp, skin or nails without rinsing or which in traces after rinsing or use. These includes:
    - Personal deodorants and antiperspirants;
    - Skin lotions, including pre-shave, after-shave, eau-de-cologne and hand lotions;
    - Creams and milky lotions, including pre-shave, after-shave, cold cream and vanishing cream;
    - Cosmetic oils;
    - Perfumes (whether liquid, solid or powder form) and toilet waters;
    - Foundations;
    - Cheek colours;
    - Eyebrow colours;
    - Nail make-up preparations (manicure and pedicure products);
    - Hair dyes, bleaches, oils, lacquers, pomades, sprays and brilliantines;
    - Sunscreen, suntan and sunburn prevention preparations;
    - Skin whitening agents;
    - Talcum, face, creamy, pressed, loose, paste, baby and body powders;
    - Hair care products, including hair tonics;
    - Depilatories;

- Hair preparations for permanent waving, setting, straightening or fixing;
- Face packs and face masks.
- Bath oils, bath salts and other bath preparations;
- Hair shampoos; hair rinses;
- Shaving foam;
- Cleansing cream;
- Face cleansing preparations and body cleansing preparations (whether cream, powder or foam); and
- Other cosmetic products which are not classified as Category 1 products

5.2.35 ASEAN Cosmetic Directive (SG)

Reference: AGREEMENT ON THE ASEAN HARMONIZED COSMETIC REGULATORY SCHEME (2003)

Organisation: Member of States of Association of Southeast Asian Nations

Importance of Article: Singapore as one of the ASEAN countries must follow the Cosmetic Directive, its annexes and appendices in order to place cosmetic products on the market in this territory

Key Points and Important Information:

- In Schedule B (Cosmetic Directive), it is stated: Member States shall undertake all necessary measures to ensure that only cosmetic products which conform to the provisions of this Directive, its Annexes and Appendices may be placed in the market.
- The ASEAN countries include The Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand and the Socialist Republic of Vietnam.

5.2.36 ANNEX II Part I of ASEAN Cosmetic Directive (SG)

Reference: ANNEX II-Part I LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE COMPOSITION OF COSMETIC PRODUCTS (2003)

Organisation: Member of States of Association of Southeast Asian Nations

Importance of Article: Lead and its compounds are listed as restricted compounds in cosmetic products composition

Key Points and Important Information:

- In this Annex (No. 289), lead and its compounds, with the exception of that mentioned in ANNEX III, n°55 under the conditions stated, are listed as substance which must not form part of the composition of cosmetic products

5.2.37 ANNEX III Part I of ASEAN Cosmetic Directive (SG)

Reference: ANNEX III-Part I LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO RESTRICTION AND CONDITIONS LAID DOWN (2003)

Organisation: Member of States of Association of Southeast Asian Nations

Importance of Article: Lead acetate may be present in cosmetic products under certain restriction

Key Points and Important Information:

- In this Annex (No. 55), Lead acetate may be present in products for hair dyeing at a maximum concentration of 0.6% in lead.
- In this case the following labeling must apply: Keep away from children, Avoid all contact with the eyes, Wash hands after use, Contains lead acetate, Do not use to dye eyelashes, eyebrows or moustaches and If irritation develops, discontinue use.

SECTION FIVE REFERENCES

- Adamson Analytical Laboratory Inc (2006) Cosmetics and Personal Care Products. <http://www.adamsonlab.com/cosmetics.htm> Accessed 2006 Apr 26
- Australasian Legal Information Institute (AustLII) (1956) Customs (Prohibited Imports) Regulations 1956 Schedule 2. http://www.austlii.edu.au/au/legis/cth/consol_reg/cir1956432/sch2.html. Accessed 2006 Feb 15.
- Australian Competition and Consumer Commission (ACCC) Cosmetics & Toiletries – ingredient labelling, product information. <http://www.accc.gov.au/content/item.phtml?itemId=323594&nodeId=file4230f150a2910&fn=Product%20safety%20guide%20-%20cosmetics%20and%20toiletries.pdf> Accessed 2006 May 24
- BSE Inquiry (2000) Volume 14: Responsibilities for Human and Animal Health Section 7. Human and veterinary medicines and cosmetics. <http://www.bseinquiry.gov.uk/report/volume14/chapted5.htm> Accessed 2006 Mar 18
- Coecke, S.; Eskes, C.; Gartlon, J.; Kinsner, A.; Price, A.; van Vliet, E.; Prieto, P.; Boveri, M.; Bremer, S.; Adler, S.; Pellizzer, C.; Wendel, A.; & Hartung, T (2005) The value of alternative testing for neurotoxicity in the context of regulatory needs. European Centre for Validation of Alternative Methods (ECVAM), Institute for Health & Consumer Protection, European Commission Joint Research Centre, Ispra (VA), Italy. <http://caat.jhsph.edu/dnt/background/Coecke%20et%20al.pdf> Accessed 2006 Apr 26
- Commission of the European Communities (1998) Three yearly report on the implementation of Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances, as amended by Directive 92/32/EEC,

<http://europa.eu.int/comm/environment/dansub/3year_rep.pdf> Accessed 28 Feb 2006

- Commission of the European Communities (1999) Commission Directive 1999/11/EC adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances. <http://www.iph.fgov.be/GLP/documents/99_11_CE.pdf#search='Council%20Directive%2087%2F18%2FEEC'> Accessed 2006 May 24
- Commission of the European Communities (2000) The Commission Directive 2000/32/EC of 19 May, 2000 adapting to technical progress for the 26th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances <http://ecb.jrc.it/Documents/Classification-Labelling/ATPS_OF_DIRECTIVE_67-548-EEC/26th_ATP.pdf#search='Commission%20Directive%202000%2F32%2FEC'> Accessed 2006 Apr 26
- Commission of the European Communities (2005) Commission Directive 2005/80/EC (21 November 2005), "amending Council Directive 76/768/EEC, concerning cosmetic products, for the purposes of adapting Annexes II and III thereto to technical progress", Official Journal L 303 , 22/11/2005 P. 0032 – 0037, <http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32005L0080:EN:HTML> Accessed 2006 Mar 7.
- Commission of the European Communities (2006) Commission Directive 2006/8/EC of 23 January 2006 amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, Official Journal L 019 , 24/01/2006 P. 0012 – 0019 <http://europa.eu.int/eur-

lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32006L0008:EN:HTML> Accessed 2006 Apr 26

- Council of the European Communities (1967) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, (OJ 196 , 16/08/1967, pages 0001 - 0098 (DE, FR, IT, NL) <http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31967L0548&model=guichett > Accessed 2006 Mar 7.
- Council of the European Communities (1976) COUNCIL DIRECTIVE of 27 July 1976 [76/769/EEC] on the approximation of the laws, regulations and administrative provisions of the Member States relating to the restrictions on the marketing and use of certain dangerous substances and preparations. Last amended 30 September 2004 <http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1976/L/01976L0769-20041018-en.pdf> Accessed 2006 Feb 26.
- Council of the European Communities (1989) Council Directive of 21 December 1989 amending Directive 76/769/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Official Journal L 398, 30/12/1989 P. 0019 – 0023, (89/677/EEC) <http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31989L0677&model=guichett> Accessed 2006 Apr 26
- Council of the European Communities (1992) Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, *Official Journal L 154 , 05/06/1992 P. 0001 - 0029* <http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31992L0032:EN:HTML> Accessed 2006 Apr 26
- Council of the European Communities (2003) DIRECTIVE 2003/15/EC OF THE EUROPEAN PARLIAMENT AND THE COUNCIL OF 27 February

2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, (OJ, 11.3.2003), <http://www.aromantic.co.uk/EU_Cosmetic_Regulations-2003-amendements.pdf> Accessed March 5 2006

- Council of the European Communities (2003) Directive 2003/15/EC of the European Parliament and The Council 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, (OJ, 11.3.2003), <http://www.aromantic.co.uk/EU_Cosmetic_Regulations-2003-amendements.pdf> Accessed 2006 Mar 5
- Council of the European Communities (2004) COUNCIL DIRECTIVE of 27 July 1976 [76/769/EEC] on the approximation of the laws, regulations and administrative provisions of the Member States relating to the restrictions on the marketing and use of certain dangerous substances and preparations. Last amended 30 September 2004 <http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1976/L/01976L0769-20041018-en.pdf> Accessed 2006 Feb 26.
- Council of the European Communities (2005) COUNCIL DIRECTIVE of 27 July 1976, on the approximation of the laws of the Member States relating to cosmetic products, (76/768/EEC), (OJ L 262, 27.9.1976, p. 169). Last amended 28th January 2005. <http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1976/L/01976L0768-20050218-en.pdf> Accessed 2006 Jan 20.
- Council of the European Communities (2005) COUNCIL DIRECTIVE of 27 July 1976, on the approximation of the laws of the Member States relating to cosmetic products, (76/768/EEC), (OJ L 262, 27.9.1976, p. 169). Last amended 28th January 2005. <http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1976/L/01976L0768-20050218-en.pdf> Accessed 2006 Jan 20.
- Economic Commission of Europe (2003) SECURITY OF THE CARRIAGE OF DANGEROUS GOODS. <http://www.efma.org/PRODUCT%20STEWARDSHIP%20PROGRAM/images/unsecurity.doc> Accessed 2006 Apr 26

- Environmental Risk Management Authority (ERMA) (2006) Components Cosmetic Products Must Not Contain. <http://www.ermanz.govt.nz/consultations/gs/cosmeticsannex2.pdf> Accessed 2006 May 3
- European Commission (1999), The rules governing cosmetic products in the European Union, Volume 1 Cosmetics legislation Cosmetic products, Office for Official Publications of the European Communities, <http://acd.ufrj.br/consumo/legislacao/nCosmetics%20legislation1.pdf#search='The%20rules%20governing%20cosmetic%20products'> Accessed 2006 Apr 26
- European Parliament and Council of the European Union (1994), European Parliament and Council Directive 94/60/EC amending for the fourteenth time Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, OJ L 365 , 31/12/1994 P. 0001 – 0009 <http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31994L0060:EN:HTML> Accessed 16 Feb 2006
- European Parliament and Council of the European Union (2005) Directive 2005/90/EC of the European Parliament and of the Council of 18 January 2006 amending, for the 29th time, Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (substances classified as carcinogenic, mutagenic or toxic to reproduction — c/m/r) Official Journal L 033 , 04/02/2006 P. 0028 – 0081 <http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=OJ:L:2006:033:0028:01:EN:HTML> Accessed 2006 Apr 26
- FDA (Food and Drug Administration) (2004) HHS § 73.2496. National Archives and Records Administration, Code of Federal Regulations <http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200221>. Accessed 2005 Dec 22.

- Food and Drug Administration (2001) CHAPTER 09 - FOOD AND COLOR ADDITIVES. Imported Foods - Food and Color Additives. <http://www.cfsan.fda.gov/~comm/cp09006.html> Accessed 2006 Apr 26
- Food and Drugs Act – Cosmetic Regulations, Updated to August 31, 2004 <http://laws.justice.gc.ca/en/F-27/C.R.C.-c.869/122960.html> Accessed 2006 Mar 8
- Health Canada (2004) Food and Drugs Act – Cosmetic Regulations, Updated to August 31, 2004 <http://laws.justice.gc.ca/en/F-27/C.R.C.-c.869/122960.html> Accessed 2006 Mar 8.
- Health Canada (2005a) Advisory - Traditional kohl products contain lead, 28th September 2005 <http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2005/2005_103_e.html> Accessed 2006 Mar 8.
- Health Canada (2005b) List of Prohibited and Restricted Cosmetic Ingredients (the Cosmetic Ingredient "Hotlist") May 2005 changes to the Cosmetic Ingredient "Hotlist" <http://www.hc-sc.gc.ca/cps-spc/person/cosmet/hotlist-change-liste_e.html> Accessed 2006 Mar 8.
- Health Canada (2005c) Food and Drugs Act. Act current to September 27, 2005 <http://laws.justice.gc.ca/en/F-27/191368.html#rid-191391> Accessed 2006 Mar 8.
- Health Science Authority [HAS] (2006) GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS. <http://www.hsa.gov.sg/docs/CCUGUIDE.V7A.pdf> Accessed: 2006 Mar 21
- International Organization of Standards (2005) Cosmetics -- Packaging and labelling. <http://www.iso.org/iso/en/CatalogueDetailPage.CatalogueDetail?CSNUMBER=36436&ICS1=71&ICS2=100&ICS3=70> Accessed 10 May 2006
- Member of States of Association of Southeast Asian Nations (2003) AGREEMENT ON THE ASEAN HARMONIZED COSMETIC REGULATORY SCHEME <http://www.hsa.gov.sg/docs/Agreement_on_the_ASEAN_Harmonised_Cosmetic_Regulatory_Scheme.pdf> Accessed 2006 Mar 22
- Member of States of Association of Southeast Asian Nations (2003) ANNEX II-Part I LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF

THE COMPOSITION OF COSMETIC PRODUCTS <http://www.hsa.gov.sg/docs/Annex_II_Prohibited_Substances.pdf> Accessed 2006 Mar 22

- Member of States of Association of Southeast Asian Nations (2003) ANNEX III-Part I LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO RESTRICTION AND CONDITIONS LAID DOWN <http://www.hsa.gov.sg/docs/Annex_III_Part_1_Restricted_Substances.pdf> Accessed 2006 Mar 22
- Office of Legislative Drafting, Attorney-General's Department (2004) Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 Statutory Rules 1991 No. 327 as amended made under the Trade Practices Act 1974. Compilation prepared 28 Sep 2004 taking into account amendments up to SR 1998 No. 364 <http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/0/F2F5C88206D4C605CA256F71004C2782/$file/TradePracCPISCos.pdf> Accessed 2005 Feb 19.
- SCCNFP (2003) Proposal for Recommended Mutagenicity / Genotoxicity Tests for the Safety Testing of Cosmetic Ingredients to be Included in the Annexes to Council Directive 76/768/EEC (SCCNFP'S Notes of Guidance) <http://europa.eu.int/comm/health/ph_risk/committees/sccp/documents/out253_en.pdf > Accessed 14 April 2006
- Secretary of State (United Kingdom) (2004) Statutory Instrument 2004 No. 2152 The Cosmetic Products (Safety) Regulations 2004. Schedule 4, Part 1, Reference No 55. Published by Queen's Printer of Acts of Parliament <http://www.opsi.gov.uk/si/si2004/20042152.htm> Accessed 2006 Mar 8.
- Therapeutic Goods Administration Department of Health and Ageing Australian Government (2005) Review of the regulation of products at the interface between cosmetics and therapeutic goods. <http://www.jtaproject.co.nz/Downloads/Hot%20Topics/CosmeticReview.pdf > Accessed 2006 Mar 21
- United Nations (2001) European Agreement Concerning The International Carriage of Dangerous Goods by Inland Waterways (ADN)

<http://www.unece.org/trans/main/dgdb/adnconf/adnfdoc/e-accord.pdf> Accessed 2006 May 17

- United Nations (2005) Restructured ADR applicable as from 1 January 2003 <http://www.unece.org/trans/danger/publi/adr/adr2003/ContentsE.html> Accessed 2006 Apr 26
- United Nations Conference on Trade and Development (UNCTAD) (2003) SINGAPORE Based on information collected up to July 2003 <http://r0.unctad.org/trains/2003%20Singapore.htm> Accessed 2006 Mar 22
- United Nations, Economic and Social Council (2006) EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR). <http://www.unece.org/trans/doc/2006/wp15/ECE-TRANS-WP15-186a1e.doc> Accessed 2006 Apr 26

6. VOLUNTARY INDUSTRY CONTROLS AFFECTING COSMETICS AND TOILETRIES

[xxx - Research required to review and summarise (as above) the following Australian and overseas industry documents and any other relevant documents you can find]

6.1 Voluntary Industry Controls in Australia

6. Voluntary Industry Controls Affecting Cosmetics and Toiletries

[xxx - Research required to review and summarise (as above) the following Australian and overseas industry documents and any other relevant documents you can find]

6.1.1 CTFAA Mission Statement

Reference: CTFAA Mission Statement
<http://www.ctfa.com.au/Templates/Mission%20Statement.cfm> Accessed 2006 Feb 20.

Organisation: Cosmetic, Toiletry and Fragrance Association of Australia (CTFAA).

Importance of Article: the Mission Statement of CTFAA may have been important in the past but although www.ctfa.com.au is still accessible on the web, when you phone their number (02 9927 7370) you are advised that they have a new number (02 9281 2322) which is actually the phone number of ACCORD (Advocate for the Consumer, Cosmetic, Hygiene & Specialty Products Industry). According to ACCORD, the CTFAA is now defunct.

Key Points and Important Information:

- "The mission of the CTFA is to represent the Australian cosmetic, toiletry and fragrance industry by promoting trust, confidence and respect for its members, consumers and government by encouraging safety, efficacy and quality."

6.1.2 ACCORD's Strategic Plan

Reference: ACCORD Strategic Plan < http://www.accord.asn.au/gui/sitemap/> Accessed 2006 Feb 21.

Organisation: ACCORD (Advocate for the Consumer, Cosmetic, Hygiene and Speciality Products Industry).

Importance of Article The ACCORD Strategic Plan outlines the Vision, Mission, Goals and Objectives of the organisation. The Goals and Objectives of the company are Member Services; Regulation and Regulatory Reform; Public Affairs; and Commercial Affairs.

Key Points and Important Information

- ACCORD's Mission is to "Promote the safe and effective use of industry products for healthy living and a quality lifestyle"
- Goal 2 of the company involves Regulation and Regulatory Reform. ACCORD aims for "A simplified and streamlined regulatory system that is…consistent with national and international best practice". Best-practice in terms of safety and industry controls involves adhering to nationally-uniform, evidence-based regulatory requirements founded on sound science.
- Goal 3 of the company is "Public Affairs" This involves "issue management" at the industry level of public health and environmental matters. They aim to "positively influence" current environmental issues including water quality, waste and packaging management, however lead is not mentioned.

6.1.3 Safety of Cosmetic Ingredients – ASCC Position Paper

Reference: Nearn, DR. M R 'Safety of Cosmetic Ingredients' Position Paper www.ascc.com.au Accessed 27th February 2006

Organisation The Australian Society of Cosmetic Chemists is a professional scientific organisation that promotes the advancement of the theory and practice of the science and technology of cosmetics, toiletries and perfumery. Membership is open to individuals who are working or interested in the cosmetics, toiletries and perfumery industry.

Importance of Article Dr Nearn's position paper outlines the regulations and processes that are used within Australia and overseas to ensure that the concentration of ingredients used within cosmetics are safe.

Key Points and important information –

Dr Nearn states "It is strongly recommended that cosmetics should not contain ingredients which have been shown to be unsafe in their conditions of use." . Before anyone states that certain cosmetics are unsafe they must "acquaint themselves with all the facts".

Dr Nearn outlines the main programs used in testing the safety of cosmetic ingredients including - Cosmetic Ingredient Review (CIR) (See Sect 6.2.1); The EEC Cosmetic Directives (See Sect5.2.7). FDA OTC (over the counter) Review Panels; IFRA (International Fragrance Association)/ RIFM (Research Institute for Fragrance Materials (No lead compounds are mentioned on www.ifraorg.org or for www.rifm.org)

The Code of Good Laboratory Practice (GLP) is the set of guidelines that all toxicology testing laboratories must follow if their results are to be accepted by government regulators. Research conducted in Australia does not have to comply with GLP. Dr Nearn however encourages its use to ensure that research in Australia is more rigorously defined, conducted and documented.

The Australian Requirements for Safe Cosmetics is also outlined including – Customs (Prohibited Imports) Regulations (see sect. 5.1.4); The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) (See sect 5.1.1); Industrial Chemicals (Notification and Assessment) Act (See sect. 1.2); The Therapeutic Goods

Administration (TGA) (See sect. 1.2); the Trade Practices Act; and Hazardous Substances and New Organisms (UNSO-NZ) Act 1999.

Dr Nearn argues that if established safety regulations are followed then adverse media publicity outlining certain cosmetic or sunscreen ingredients as unsafe will remain unfounded. The cosmetic industry has to much lose from selling an unsafe product.

6.1.4 Colorants for Cosmetics and Personal Care Products (other than hair dyes) –ASCC Position Paper

Reference: Hancock, John, 'Colorants for Cosmetics and Personal Care Products', September 2000. ASCC Position Paper <www.ascc.com.au> Accessed 2006 Mar 8.

Organisation: The Australian Society of Cosmetic Chemists is a professional scientific organisation that promotes the advancement of the theory and practice of the science and technology of cosmetics; toiletries and perfumery. Membership is open to individuals who are working or are interested in the cosmetics, toiletries and perfumery industry.

Importance of article: First prepared by the ASCC Colour Working Party in 1989, Hancock has updated the paper and incorporated the latest local and international regulations. The aim of the position paper is to ensure that ASCC members can identify any colour cosmetics and determine its regulatory status.

Key Points and Important Information:

Both the ASCC and the CTFAA recommend that only colorants, which are permitted in the European EU Cosmetics Directives (Reference 1) and or the USA FDA listings (Reference 2), should be used for cosmetic and personal care applications

In Australia, cosmetic colorants must be included in the Australian Inventory of Chemical Substances (AICS), but there is no positive list of colorants for use in cosmetics and personal care products. Some of the colours in AICS may have been included as part of the original grandfathering of chemicals and may not have been subject to rigorous review. In the USA and EU, colours have been subject to

extensive toxicological review and it is recommended that members refer to these lists when selecting colorants for use in personal care product

The ASCC Technical Committee strongly advises that while we believe the list to be correct, the regulatory status of any coloring agent may change and should be checked prior to use.

If the coloring agent is not in this Australian Inventory List, it cannot be imported into Australia either as a Raw Material or included in a Finished Imported Product.

Hancock has not specified in his article which colorants contain lead. xxx Josephine please summarise the tables in the Hancock article to specify reference to lead

6.2 Voluntary Industry Controls Overseas

6.2.1 Cosmetics Ingredient Review (CIR)

Reference: Cosmetic Ingredient Findings – 1976 to Current. Last updated 2005 Sep 16th. <http://www.cir-safety.org/findings.shtml>. Accessed 2005 Dec 15.

Organisation: CIR (Cosmetics Ingredient Review). Cosmetic ingredients are reviewed by the Cosmetic Ingredient Review (CIR), established in 1976 by the Cosmetic, Toiletry & Fragrance Association (CTFA) with support of the U.S. Food & Drug Administration. CIR is an independent, non-profit scientific body that holds open public meetings and publishes its findings in a peer reviewed journal. Its seven voting medical and scientific members must meet the same conflict of interest standards as persons serving on the FDA's outside advisory committees. FDA, the Consumer Federation of America, and industry serve as liaison members on the CIR Expert Panel.

Importance of Article: The Cosmetic Ingredient Review, provides cosmetic ingredients information on its web site (CIR 2005). The report consists of the finding on the safety of ingredients found in cosmetics –for example the following items where lead is mentioned – see TABLE 12.

- xxx

TABLE 12: Cosmetic Ingredient Review Information on Leaded Ingredients

Ingredients	Qualifications
Acid Violet 43	Safe for use in hair dye formulations when free of impurities except for the following: #18% volatile matter (at 135°C) and chlorides and sulfates (calculated as sodium salts); #0.4% water-insoluble matter; #0.2% 1-hydroxy-9,10-anthracenedione; #0.2% 1,4-dihydroxy-9,10-anthracenedione; #0.1% p-toluidine; #0.2% p-toluidine sulfonic acids, sodium salts; #1% subsidiary colors; #20 ppm lead (as Pb); #3 ppm arsenic (as As); #1 ppm mercury (as Hg); and $80% total color.
Cottonseed Acid, Cottonseed Glycerides, and Cottonseed (Gossypium) Oil	Safe as used, provided that established limitations imposed on gossypol, heavy metal and pesticide concentrations are not exceeded (Gossypol limited to a concentration < 450 ppm; heavy metal limitations are lead #0.1 mg/kg, arsenic#3 ppm (as As), and mercury #1 ppm (as Hg); PCB/pesticide contamination limited to not more than 3 ppm with not more 1 ppm for any specific residue)
Hydrogenated Cottonseed Glyceride And Hydrogenated Cottonseed Oil	Safe as used, provided that established limitations imposed on gossypol, heavy metal and pesticide concentrations are not exceeded (Gossypol limited to a concentration < 450 ppm; heavy metal limitations are lead # 0.1 mg/kg, arsenic# 3 ppm (as As), and mercury # 1 ppm (as Hg); total PCB/pesticide contamination limited to not more than 3 ppm with not more 1 ppm for any specific residue)
Lard Glyceride, Lard Glycerides, Lard, Hydrogenated Lard Glyceride,	Safe as used, provided that established limitations on heavy metals and pesticide concentrations are not exceeded (Lead is limited to not more than 0.1 mg/kg (0.1 ppm); arsenic (as As) limited to # 3 ppm and mercury (as

Hydrogenated Lard Glycerides, and Hydrogenated Lard	Hg) to # 1 ppm. Total PCB/pesticide contamination limited to not more than 40 ppm with not more than 10 ppm for any specific residue)

"The color additive lead acetate may be safely used in cosmetics intended for coloring hair on the scalp only, subject to the following restrictions:
The amount of the lead acetate in the cosmetic shall be such that the lead content, calculated as Pb, shall not be in excess of 0.6 percent (weight to volume).
The cosmetic is not to be used for coloring mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp." (FDA xxx date?)

- [xxx research required as to whether there are other North American voluntary industry controls on lead in cosmetics at Cosmetic Data Base <http://www.cosmeticsbusiness.com> or <http://www.ifraorg.org> or <http://www.rifm.org>]

Europe

[xxx research required]

United Kingdom

[Xxx research required – see The Chemical Industries Association www.cia.org.uk and Formulators Discussion Group www.stepex.co.uk

SECTION SIX REFERENCES

- <http://www.accord.asn.au>
- <http://www.austrade.gov.au>
- [xxx – other references?]