File No: LTD/1197

21 July 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

2(3H)-Furanone, dihydro-3-hydroxy-4,4-dimethyl-

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Henkel Australia Pty. Limited (ABN 82 001 302 996)
20 Rodborough Rd,
Frenchs Forest
NSW 2086

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Identity of impurities
Spectral data
Purity
Site of reformulation
Percentage of notified chemical in end-use preparations
Import volumes

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
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Hydrolysis as a function of pH
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Particle size
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Explosive properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
No

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
2(3H)-Furanone, dihydro-3-hydroxy-4,4-dimethyl-

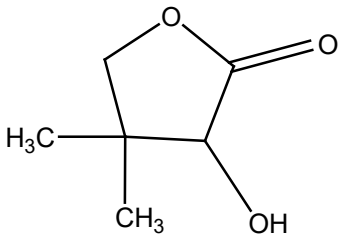
OTHER NAME(S)
(±)-Dihydro-3-hydroxy-4,4-dimethylfuran-2(3H)-one
d,l-Pantolactone
(±)-Pantoyl lactone

MARKETING NAME(S)
Pantolactone

CAS NUMBER
79-50-5

MOLECULAR FORMULA
$C_6H_{10}O_3$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
130.14

SPECTRAL DATA

Remarks An infrared (IR) spectrum was provided

METHODS OF DETECTION AND DETERMINATION

Remarks Analysed by GC and titration.

3. COMPOSITION

DEGREE OF PURITY
> 95 %

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Information on impurities provided.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)
None known.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported neat as a solid in 22 kg polyethylene buckets. Alternatively, the notified chemical will be imported as a component of ready to use hair care products. The notified chemical will be present at < 1% in the finished products.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 1	< 1	< 1	< 1	< 1

USE
The notified chemical will be used as a component of varied types of hair care products. It will be used in both “wash-off” and “leave on” products, including shampoos, conditioners, mousses, hairsprays, tonics and gels..

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney, NSW

TRANSPORTATION AND PACKAGING
The notified chemical will be shipped into Sydney, Australia at neat concentration in 22 kg polyethylene buckets. The notified chemical will be transported from the dockside to the formulation site, where it will be stored and formulated into hair care products. The finished hair care products will be packaged into small sealed consumer sized containers i.e. 125, 175, 250 or 400 mL plastic bottles. These plastic bottles are then sealed with plastic closures and packed in cardboard cartons before being transported by truck or van to end-users (hair salons, retail outlets).

The notified chemical will also be imported as a component of ready to use hair care products in 125 to 400 mL plastic bottles. The packaged goods will be transported by road from the wharf to the notifier's warehouse where it will be stored prior to distribution by road to retail and hair salon outlets.

5.2. Operation description

Formulation in Australia
The notified chemical will be transported by road in 22 kg polyethylene buckets to the formulation site at Ingleburn, NSW, where it will be stored and formulated into hair care products.

During manufacture of hair shaping products, an operator will open the polyethylene buckets, weigh and add the required amount of the notified chemical into a mixing vessel. Other ingredients will also be added and the mixture is blended in either an open or closed mixing vessel. Mixing operation is automated. Prior to packaging, sampling and quality testing of the hair shaping products are carried out in the laboratory. The formulated products will then be transferred by pump into a storage tank connected to a multiple head filler machine and automatically poured into screw cap or push on caps plastic bottles.

Depending on the type of hair care products, the mixture is packed in 125, 175, 250 or 400 ml plastic containers. The bottled products will be sealed with plastic closures and packed in cardboard cartons and will be transported to distribution warehouses for retail outlets, who will subsequently supply the products to retail outlets for consumer use.

Import of packaged consumer products
Alternatively, the notified chemical will be imported as a component of ready to use hair care products, for distribution to retail outlets for consumer use. Retail workers will handle the finished products in their retail packaging.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transporting and warehousing	5-10	2-3 hours/day	50 days/year
Operators	20-50	8 hours/day	230 days/year
Laboratory technicians	2	2-3 hours/day	230 days/year
Maintenance	3	2-3 hours/day	10 days/year
Hair salon and retail outlet workers	> 1000	1 hour per day	200-240 days per year

Exposure Details
Importation, Transport and Storage
Exposure is not expected to workers involved in the importation, storage and transport of the notified chemical, except in the unlikely event of an accidental spill. Gloves, coveralls and goggles are available if required.

Formulation of Preparation
Dermal, ocular and inhalation exposure to the notified chemical (100%) may occur during opening of the polyethylene buckets, weighing and adding the required amount of the notified chemical into a mixing vessel and connecting and disconnecting transfer and filling lines. Following reformulation any exposure will be to products containing up to 0.5% of the notified chemical. Exposure to the finished product is most likely during packaging and unitising of finished consumer products.

The mixing vessels are enclosed and the filling machines are automated and fitted with local exhaust ventilation to capture any dust generated at the source. To prevent exposure workers wear overalls, dust mask, safety glasses and/or safety shoes and impervious gloves.

Quality Control/Maintenance
Limited dermal exposure to small quantities may occur during sampling and testing or during machine maintenance. To minimise exposure workers will wear laboratory coats, safety glasses and rubber gloves.

End-Use
Dermal, and inadvertent ocular exposure may occur in those professions (e.g. hair dressers) where the services provided involve the application of personal care products.

EDUCATION & TRAINING
All personnel professionally involved in the handling and use of products containing the notified polymer will have access to the Material Safety Data Sheet.

PREVALENCE OF WORK-RELATED INJURIES & DISEASES
No adverse health effects arising from human exposure to the notified polymer have been observed or reported

OTHER OCCUPATIONAL HAZARDS
No injuries or diseases related to exposure to the notified polymer are known. The notified polymer is not known to exacerbate any existing health conditions.

OCCUPATIONAL HEALTH MONITORING (BIOLOGICAL MONITORING & ATMOSPHERIC MONITORING)
No biological or atmospheric monitoring is proposed.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will be transported from the dockside to the formulation site, where it will be stored and formulated into hair care products. Release volumes from the formulation process are expected to be low. During the formulation of hair care products the estimated annual losses of notified chemical are:

Release source	%	kg
Spills	< 1%	<10
Equipment cleaning	< 3%	<30
Import container residuals	< 1%	<10
Total annual loss		<50

All the reformulation waste will be treated in an on-site treatment plant. It will be neutralised and the solids removed for disposal to landfill and the liquid effluent will be discharged as trade waste.

RELEASE OF CHEMICAL FROM USE
Following application of hair care products, almost all of the notified chemical will be washed from hair and released to sewer. The end use containers are expected to be disposed of with normal domestic garbage to landfill. The residues of notified chemical remaining in these bottles are expected to be 2% or up to 20 kg per annum.

5.5. Disposal

The majority of notified chemical will be washed off hair and will enter the sewer. Residual chemical in containers is expected to account for less than 3% per annum of total imported notified chemical. Import containers are expected to be disposed of to drum recyclers, where any residual notified chemical will be removed and thermally decomposed in high temperature incinerators. End use containers are expected to be disposed of as domestic waste to landfill.

5.6. Public exposure

The notified chemical will be used in the manufacture of hair care products, which will be available to the public through hair salon and retail outlets. Public exposure will be widespread and will result through the use of hair care products containing < 1% notified chemical. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified chemical. In most cases exposure is expected to be limited to 5 grams (< 0.05 grams of notified chemical), assuming usage twice a day.

Public exposure during transport, storage and retail distribution is unlikely unless the packaging is breached.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White to pale yellow waxy solid

Melting Point/Freezing Point 74-78°C

Remarks Data above is from MSDS. IUCLID Data Set for α-Hydroxy- β, β -dimethyl- γ – butyrolactone (d isomer) cites melting point as 91-92°C (IUCLID, 2000b).

Boiling Point 246.8°C at 101.3 kPa

Remarks Information from IUCLID Data Set for α-Hydroxy- β, β -dimethyl- γ – butyrolactone (d isomer) (IUCLID, 2000b). The MSDS for the notified chemical notes that the chemical decomposes at or prior to boiling.

Density 941.5 kg/m^3 at 20°C

Remarks Information from IUCLID Data Set for α-Hydroxy- β, β -dimethyl- γ – butyrolactone (d isomer) (IUCLID, 2000b)

Vapour Pressure 0.5578 kPa at 100°C
141.5 kPa at 260 °C

Remarks Information from IUCLID Data Set for α-Hydroxy- β, β -dimethyl- γ – butyrolactone (d isomer) (IUCLID, 2000b)

Water Solubility Soluble

Remarks Calculated using ACD Software. In addition, the MSDS for the notified chemical states that the water solubility at 20^0C is > 95% w/w. EPIWIN estimates the water solubility to be 1 X 10^6 mg/L.

Hydrolysis as a Function of pH

Remarks Stable in aqueous solution at pH 5.5. May undergo hydrolysis of the lactone ring.

Partition Coefficient (n-octanol/water) Log K_{OW} = -0.97

Remarks Estimated using a structural fragment method, as listed in the product MSDS. Log K_{OW} = -0.97 (KOWWIN v1.66 estimate). Log P_{OW} = -0.80 ± 0.37 (Calculated using ACD Software).

Adsorption/Desorption Not determined

Remarks Log K_{OC} = 0.9 ± 1.0 (Calculated using ACD Software). Log K_{OC} = 0.000 (Estimated by PCKOCWIN v1.66).

Dissociation Constant Not determined.

Remarks The chemical does not contain groups that can undergo dissociation.

Particle Size Not determined

Remarks Supplied in flake form.

Flash Point /Solid flammability Not determined

Flammability Limits Not determined

Remarks Not relevant as the notified chemical is a solid.

Autoignition Temperature Not determined

Explosive Properties Not determined

Remarks Not expected to be explosive.

Reactivity

Remarks Stable in aqueous solution at pH 5.5. The MSDS for the notified chemical notes that the chemical is hygroscopic. It recommends avoidance of elevated temperatures, strong acids or bases, reducing agents and strong oxidising agents.

7. TOXICOLOGICAL INVESTIGATIONS

No study reports were submitted. The sources of toxicological information used in this assessment are listed below:

The IUCLID Data Sets for DL-Pantolactone (the notified chemical) (IUCLID, 2000a) and D-Pantolactone (IUCLID, 2000b) each report two acute oral toxicity studies on the respective chemicals, one in rats and one in mice. These data sets also indicate that DL-Pantolactone and D-Pantolactone are irritating to the skin and eyes.

A BIBRA review of all isomers of pantolactone (BIBRA, 1995) contained information on acute toxicity and mutagenicity.

A published paper (Wolfreys & Basketter, 2004) reported on the skin sensitisation potential and mutagenicity of DL-Pantolactone.

Material tested	*Endpoint and Result*	*Assessment Conclusion*
DL- Pantolactone	Rat, acute oral LD50 9700 mg/kg bw	Low toxicity
	Mice, acute oral LD50 4380 mg/kg bw	Low toxicity
D-Pantolactone	Rat, acute oral LD50 3360 mg/kg bw	Low toxicity
	Mice, acute oral LD50 1410 mg/kg bw	Harmful
DL- Pantolactone	Rabbit, skin irritation	Irritating
DL- Pantolactone	Rabbit, eye irritation	Irritating
D-Pantolactone	Rabbit, skin irritation	Irritating
D-Pantolactone	Rabbit, eye irritation	Irritating
DL- Pantolactone	Skin sensitisation – guinea pig test or LLNA – method not specified.	Non-sensitising
DL- Pantolactone	Genotoxicity - bacterial reverse mutation	Negative
Pantolactone (isomer not specified)	Genotoxicity - bacterial reverse mutation in *Escherichia coli*	Negative
DL- Pantolactone	Genotoxicity – in vitro chromosomal aberration	Negative

7.1. Acute toxicity

The LD50 by the oral route of DL-pantolactone was reported to be 9700 mg/kg bw in rats and 4380 mg/kg bw in mice (IUCLID, 2000a). For D-pantolactone the corresponding LD50 values were 3360 mg/kg bw in rats and 1410 mg/kg bw in mice (IUCLID, 2000b).

BIBRA (1995) summarised further acute toxicity studies by other routes. The intraperitoneal LD50 of D-pantolactone in mice was 600 mg/kg bw. By the same route 0.06 mg/kg bw did not affect the level of "the acetylation coenzyme" in the liver or brain of mice. In another study by either intraperitoneal or intravenous injection, tonic convulsions (which usually cause death) occurred from doses of 1000 mg/kg bw upwards. Clonic convulsions occurred at doses above 250 mg/kg bw.

7.4. Irritation – skin

DL-Pantolactone and D-Pantolactone were reported to be irritating to skin (IUCLID 2000a, IUCLID, 2000b).

7.5. Irritation – eye

DL-Pantolactone and D-Pantolactone were reported to be irritating to eyes (IUCLID 2000a, IUCLID, 2000b).

7.6. Skin sensitisation

Wolfreys & Basketter (2004) reported on unpublished sensitsation data from industry in-house databases, based on either the guinea pig maximisation test or the LLNA. Results were determined by European Union classification criteria. DL-Pantolactone was not a sensitiser by these criteria.

7.8. Genotoxicity –

Wolfreys & Basketter (2004) reported on the results of mutagenicity screening of DL-pantolactone, from information in industry databases. In most cases the test screens used the bacterial mutagen assay and

chromosome aberration tests with human peripheral lymphocytes, and in some cases other data was used. Testing was according to OECD guidelines. DL-pantolactone was reported to be negative in this screening.

BIBRA (1995) reported a study in which pantolactone was not mutagenic tin *Escherichia coli* bacteria. However no further details were given.

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted, however, the following were taken from IUCLID or estimated using EPIWIN Suite of Modelling software.

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified Chemical
RESULTS	Biologically easily degradable Zahn-Wellens-Test: 98% (OECD 302B) Modified MITI Test I: 100% Modified MITI Test II: 86% Source: F. Hoffmann-La Roche AG Dalry (as published in the IUCLID). Supported by estimations using BIOWIN v4.00: Linear Model Prediction:..... Biodegrades Fast Non-Linear Model Prediction: ..... Biodegrades Fast Ultimate Biodegradation Timeframe:..... Weeks Primary Biodegradation Timeframe:.....Days MITI Linear Model Prediction: ..... Biodegrades Fast MITI Non-Linear Model Prediction: ..... Biodegrades Fast

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted, however estimates were made using EPIWIN modelling software.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified Chemical
METHOD	ECOSAR Program (v0.99g)
RESULTS	
LC50	764 mg/L at 96 hours.
CONCLUSION	According to the classification scheme proposed by Mensink *et al* (1995), the notified chemical has been estimated to be very slightly toxic to fish.

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified Chemical
METHOD	ECOSAR Program (v0.99g)
Species	*Daphnia magna*
RESULTS	
LC50	52135 mg/L at 48 hours
CONCLUSION	According to the classification scheme proposed by Mensink *et al* (1995), the notified chemical has been estimated to be very slightly toxic to aquatic invertebrates.

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified Chemical
METHOD	ECOSAR Program (v0.99g)
RESULTS	
EC50	55 mg/L at 96 hours
CONCLUSION	According to the classification scheme proposed by United Nations (2003), the notified chemical has been estimated to be harmful to algae.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Environmental exposure of the notified chemical will result from reformulation and use of the notified chemical as well as from the disposal of import and end-use containers. It is expected that the entire import volume will be released to the environment.

The notified chemical is estimated to be moderately volatile (Vapour Pressure = 0.055 Pa), according to the classification scheme proposed by Mensink *et al* (1993), and therefore, some may dissipate into air from water, with an estimated half-life of 3.233 days (AopWin v1.90). It is estimated to be water-soluble and is expected to remain within the aquatic environment based on its estimated Henry's Law constant of 2.82 x 10^{-5} atm-m^3/mole (log H –4.55), but will not readily hydrolyse in natural waters at environmental pH values. The estimated low log Kow (-0.97) is consistent with the high water solubility indicating a low affinity for the organic phase and component of soils and sediments. It may be highly mobile in soil due to high water solubility. The notified chemical is readily biodegradable. Incineration of the notified chemical will destroy the compound with the generation of water vapour and oxides of carbon.

A predicted environmental concentration (PEC) in the aquatic environment is estimated below using a worst-case scenario where the entire import volume (the maximum of 1000 kg) of the notified chemical will be discharged to sewer. It is further assumed that none is attenuated within the sewage treatment plants (STP), and the daily release on a nationwide basis to receiving waters is estimated to be 2.74 kg/day.

Amount released to sewer:	1000 kg
Population of Australia:	20.1 Million
Water use per person per day:	200 L
Number of days used:	365
PEC_{Sewer}:	0.68 µg/L
PEC_{River} (Dilution Factor = 1):	0.68 µg/L
PEC_{Ocean} (Dilution Factor = 10):	0.07 µg/L

The notified chemical is readily biodegradable. Its Henry's Law Constant of 2.82 x 10^{-5} atm-m3/mole (log H –4.55) and log Kow of -0.97 were applied in the SIMPLETREAT model (European Commission 2003) for modelling partitioning and losses in STPs. The results indicate that when 1000 kg of the notified chemical is released into the aqueous phase of a STP, 0% released to air through volatilisation, 0% partitioned to biosolids, 33% (333 kg) partitioned to water and 67% will be degraded. Therefore, the PECs of the notified chemical in effluent released, freshwater and marine water will be approximately 0.23, 0.23 and 0.02 µg/L, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m^3). Using these assumptions, irrigation with a concentration of 0.23 µg /L may potentially result in a soil concentration of approximately 2.2 X 10^{-3} mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 1.1 X 10^{-2} mg/kg and 2.2 X 10^{-2} mg/kg, respectively.

Due to the low log P_{ow} and the high water solubility of the notified chemical, its potential for bioaccumulation is low in exposed aquatic organisms.

9.1.2. Environment – effects assessment

A predicted no effect concentration (PNEC - aquatic ecosystems) of 55 µg/L has been derived by dividing the end point value of 55 mg/L (Green algae) by a worst-case scenario uncertainty (safety) factor of 1000. Use of this safety factor is also appropriate as no ecotoxicity data were

provided and estimated ecotoxicity data have been used.

9.1.3. Environment – risk characterisation

	River	Ocean
PEC	0.68 µg/L	0.07 µg/L
PNEC	55 µg/L	55 µg/L
RQ (PEC/PNEC)	4.1 X 10^{-3}	4.1 X 10^{-4}

The worst case (no attenuation) RQ values (PEC/PNEC) derived for the aquatic environment are very low and well below 1 for both freshwater and marine waters, indicating no immediate concern to the aquatic compartment. Bioaccumulation is not expected from the diffuse use pattern and low import volume.

Based on the proposed use pattern the notified chemical is not expected to pose an unacceptable risk to the health of aquatic life.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport & Storage

Occupational exposure to the notified chemical during its transport and storage, or of finished products containing < 1% notified chemical, is only likely in the event of accidental container spillage involving breach of packaging. Exposure in these circumstances is expected to be infrequent and limited by use of appropriate personal protective equipment (PPE) during clean-up operations.

Reformulation and packaging

Worker exposure to the notified chemical during reformulation into hair care products may occur when weighing the notified chemical and adding it to the mixing vessel, and also during sampling for QA testing. Any exposure is expected to be primarily dermal. Ocular exposure is less likely because the chemical is supplied as solid pellets, however this may also occur as a result of spills or as secondary to skin contamination. Inhalation exposure is not expected to occur in these processes.

Exposure to products containing < 1% of the notified chemical during mixing and filling operations is expected to be low, as the concentration is low, and exposure is limited by engineering and PPE controls.

End-use in salons

Dermal and ocular exposure to workers can occur when products containing < 1% of the notified chemical are dispensed and applied to customers' hair. Exposure would be limited by use of gloves and safe work practices. Inhalation exposure could also occur if any of the products were applied by spraying.

9.2.2. Public health – exposure assessment

Widespread public exposure is expected to hair care products containing < 1% of the notified chemical. The main potential route of exposure would be dermal, through scalp and hands. Some accidental ocular exposure is also possible. Inhalation exposure could also occur if any of the products were applied by spraying. "Leave-on" products are expected to have the greatest potential for dermal exposure, because they would be in contact with the scalp for a longer period.

9.2.3. Human health – effects assessment

Little data are available on the notified chemical. Where available, information on the D-isomer analogue or on unspecified isomers of pantolactone has also been considered.

BIBRA (1995) reported that pantolactone had been shown to interact with cell membranes in the bacterium *Micrococcus lysokeikticus* and that this effect may be related to the stimulatory effect

of the chemical on cell division. They noted also that D-pantolactone is a degradation product of the B-complex vitamin D-pantothenic acid, which occurs widely in animal and plant tissue.

Based on limited data the notified chemical is of low acute toxicity via the oral route, with low to moderate toxicity for the D-isomer analogue.

The notified chemical is stated to be irritating to the skin and eyes, however no indication was given of the severity of the effects. It is reported not to be a skin sensitiser, based on EU classification criteria.

The notified chemical was found not to be mutagenic in unpublished studies undertaken in accordance with international test guidelines. The D-isomer was reported to be non-mutagenic in one bacterial strain.

The notifier advised that no adverse health effects to workers arising from exposure to the notified chemical have been observed.

Based on the limited available data, the notified chemical cannot be classified for human health effects in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Only limited data are available on the health effects of the notified chemical. The data suggest that the chemical is of low oral toxicity, and is not a sensitiser or mutagen. It may cause skin and eye irritation, however these effects would be greatly mitigated by the low concentration of the notified chemical in formulated hair products.

Skin and eye irritation could result from worker exposure to the notified chemical. It is expected that the risk would be controlled by appropriate engineering measures, PPE and safe work practices at the reformulation sites, and for cleanup of any accidental spillage in transport or storage.

Similarly, use of PPE for those workers in contact with products containing the notified chemical at < 1% in salons or at the reformulation sites is expected to reduce any risk from dermal or ocular exposure to low levels. Additional inhalation exposure to salon workers could occur if the notified chemical was used in sprayed products.

Overall the risk to workers is considered low, based on the known toxicity and potential for exposure. However it should be noted that a full toxicological profile of the chemical is not available.

9.2.5. Public health – risk characterisation

Only limited data are available on the health effects of the notified chemical. This data showed low oral toxicity and negative results for skin sensitisation and mutagenicity. Any potential irritation to skin or eyes is expected to be mitigated by the low concentration in products used by the public.

The notified chemical contains a lactone group, that may hydrolyse under certain conditions. The notifier has advised that the proposed pH of the formulated hair products is 5.5, and that the chemical is stable at this pH.

Based on its intended use and the low concentration of the notified chemical, it is considered that the notified chemical will not present a risk to public health. However it is noted that a full toxicological profile of the chemical is not available.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

As only limited data is available on the notified chemical, it cannot be classified for health effects under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

It is noted that the overseas MSDS for the notified chemical states that it is not hazardous to health and environment according to EC criteria.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used as a component of hair care products at < 1%.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and a product containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical and a product containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical itself, however, these should be selected on the basis of all ingredients in the formulation.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- The following measures should be taken by formulators of hair care products to minimise public exposure to any breakdown products of the notified chemical:
  - Stability testing of proposed formulations; and
  - Monitoring of pH of formulations to ensure stability of the notified chemical.

Environment

Disposal

- The notified chemical should be disposed of by thermal decomposition in high temperature incinerators or to secure landfill.

Emergency procedures

- Spills/release of the notified chemical should be handled by physical containment, collection and subsequent disposal by thermal decomposition in a high temperature incinerator or to secure landfill.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical; or
  - the notified chemical is used in personal care products at > 1%.

or

(2) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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