

File No: NA/645

February 1999

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION  
AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**LC-2**

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, National Occupational Health and Safety Commission, 92-94 Parramatta Road, Camperdown NSW 2050, between the following hours:

Monday - Wednesday	8.30 am - 5.00 pm
Thursday	8.30 am - 8.00 pm
Friday	8.30 am - 5.00 pm

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

For enquiries please contact the Administration Coordinator at:

*Street Address:* 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA

*Postal Address:* GPO Box 58, Sydney 2001, AUSTRALIA

*Telephone:* (61) (02) 9577-9514 FAX (61) (02) 9577-9465

Director  
Chemicals Notification and Assessment

**FULL PUBLIC REPORT****LC-2****1. APPLICANT**

Goldwell Cosmetics (Australia) Pty Limited of 103 Yerrick Rd LAKEMBA NSW 2195 has submitted a limited notification statement in support of their application for an assessment certificate. The applicant has not applied for any information relating to LC-2 to be exempt from publication in the Full Public and Summary Reports.

**2. IDENTITY OF THE CHEMICAL**

**Chemical Name:** 1,3-propanediol, 2-(hydroxymethyl)-2-[[2-hydroxy-3-(iso-octadecyloxy) propoxy] methyl]

**Chemical Abstracts Service (CAS) Registry No.:** 146925-83-9

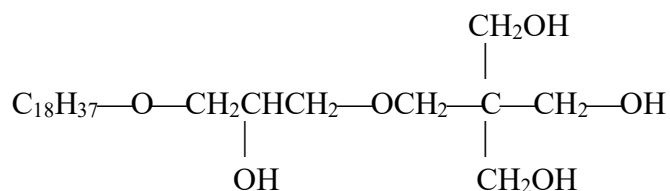
**Other Names:** 1-O-octadecyl-3-O-[2-tris (hydroxymethyl) ethyl] glycerol

Isostearyl pentaerythryl glyceryl ether

**Trade Name:** LC-2

**Molecular Formula:** C<sub>26</sub>H<sub>54</sub>O<sub>6</sub>

**Structural Formula:**



Note: The C<sub>18</sub>H<sub>37</sub>- moiety (iso-octadecyl) is probably a complex mixture of various structural isomers

**Molecular Weight:** 462.7

**Spectral Data:** infrared spectroscopy: major peaks were observed at: 3 388, 2 932, 2 866, 1 464, 1 116 and 1 038 cm<sup>-1</sup>

**Method of Detection and Determination:** GC, HPLC and infrared spectroscopy

### 3. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20°C and 101.3 kPa:** colourless to light yellow paste

**Boiling Point:** 272-274°C

**Specific Gravity:** 0.95 at 70°C

**Vapour Pressure:** 3.343 x 10<sup>-7</sup> kPa at 25°C

**Water Solubility:** 74 mg/L at 20°C

**Partition Co-efficient (n-octanol/water):** log K<sub>ow</sub> > 3.75 at 20°C (estimate)

**Hydrolysis as a Function of pH:** Some hydrolytic degradation at pH 7, and slower degradation at pH 4 and pH 9 - see notes below

**Adsorption/Desorption:** no data provided - see notes below

**Dissociation Constant:** no data provided - see notes below

**Flash Point:** 251°C

**Flammability Limits:** not flammable

**Explosive Properties:** none

**Reactivity/Stability:** stable

#### Comments on Physico-Chemical Properties

No test reports or references to the test methods employed for determination of the physico-chemical properties accompanied the notification.

The new chemical does not contain bonds that are easily hydrolysed under normal aquatic environmental conditions.

The log  $K_{ow}$  was estimated (presumably via quantitative structure activity relationship (QSAR) calculations) as greater than 3.75 and indicates that the material is moderately hydrophobic. This is in general accord with the molecular structure which shows the molecule to possess a large hydrophobic iso-octadecyl moiety coupled through 1,3-propanediol ether linkages to a pentaerythritol residue which has considerable affinity for water through the presence of the pendant hydroxy groups. However, the moderately high value for log  $K_{ow}$  indicates the chemical would partition into oils and fats.

No adsorption/desorption data was provided, since relevant tests could not be performed due to the surface active nature of the chemical. However, the moderately hydrophobic nature of the material indicates that it would associate with the natural organic component of soils and sediments, and become incorporated in these materials.

The compound contains no functionalities capable of readily dissociating in aqueous media, so dissociation constant data are not applicable.

Although no surface tension data were included in the submission, the chemical could be expected to be appreciably surface active due to the combination of the large hydrophobic hydrocarbon group with the moderately hydrophilic pentaerythritol residue in the same molecule.

Calculations based on the molecular structure using the QSARs of the US Environment Protection Agency ASTER database (US Environment Protection Agency, 1998) furnished the following estimates for environmentally relevant physico-chemical parameters. Where comparison with data supplied by the notifier is possible, the agreement is reasonable.

#### **ASTER Data**

<b><u>Property</u></b>	<b><u>QSAR Estimate</u></b>
Boiling Point:	498°C
Vapour Pressure:	$4.7 \times 10^{-13}$ mm of Hg
Water Solubility:	40.7 mg/L
log $K_{ow}$ :	3.94
log $K_{oc}$ :	3.48

#### **4. PURITY OF THE CHEMICAL**

**Degree of Purity:** 73% (65-85%)

**Toxic or Hazardous Impurities:** none

**Non-hazardous Impurities  
(> 1% by weight):**

<i>Name</i>	<i>CAS Number</i>	<i>% Weight</i>
2,2-bis [2-hydroxy-3-(iso-octadecyloxy)-propoxyl] methyl]-1,3-propanediol	146925-84-0	19%; (max. 27%)*
iso-octadecanol	27458-93-1	2%; (max 4%)
glycerol monoisostearyl ether	78145-84-3	2%; (max 6%)
pentaerythritol	115-77-5	1%; (max 2%)
water	7732-18-5	0.5%; (max 1%)

\* The notifier has confirmed that this high percentage impurity is not likely to contribute to the function of the notified chemical

**Additives/Adjuvants:** none

## **5. USE, VOLUME AND FORMULATION**

The notified chemical is to be used as a moisturiser in manufactured hair care products. It will be imported in 20 kg plastic drums at a rate of approximately 200 kg/annum for the first five years. Approximately half the imported amount will be used in a hair straightener for export. The remainder is to manufacture hair conditioner for sale to hair salons as a professional use product (50%) and a retail product (50%).

## **6. OCCUPATIONAL EXPOSURE**

The imported drums will be transported to the notifier's warehouse prior to shipping to a single customer. Waterside, transport drivers and warehouse workers should only be exposed in the event of accidental spillage. Two to four workers will be involved for 2-3 hours/day, 10-15 days/year.

Compounding of hair care products, for export and domestic use, by 2-4 workers will take place for 1-2 hours per day, up to 200 days per year. A compounder will dispense the required amount of the notified chemical from the imported plastic drum manually and weigh it out in a ventilated flameproof area. Dermal exposure to the chemical (in the form of a paste) is possible while removing it from the drum and transferring it to the mixing vessel. Mixing with other raw materials, filling and packaging into tubes or 250 mL plastic bottles (at a final concentration of 0.2-1%) takes place in an automated closed system so that exposure is only possible during machine maintenance. The notifier states that compounders will be required to wear chemical safety glasses and protective gloves.

Approximately 50% of the imported chemical will be used to formulate hair conditioner sold to hair salons. The salons will sell about 50% of the product to the public and use the remainder themselves. Potentially, there are 5 000 salons across Australia which may use the hair conditioner. Each of these salons may employ 2-10 workers. As a worst case estimate, each worker may use the hair conditioner on a client every 30 minutes for 5 minutes over the working day. The equates to 307 hours per year (1.3 h/day x 230 days/yr). The nature of the work involves the application of the hair conditioner to the client's hair, massaging it into the

hair prior to rinsing out the conditioner with water. According to the notifier some workers use rubber gloves for the operation but the use of gloves is not compulsory. In addition a nylon apron is used over clothing and the work is carried out in a well ventilated area.

## **7. PUBLIC EXPOSURE**

### **Transportation**

Although spillage is possible during a transport accident, the paste-like consistency of the notified chemical will limit its dispersion and aid its recovery.

### **Consumer product manufacture**

As the manufacturing process is limited to the mixing of product ingredients, and the subsequent pumping and packaging of the end consumer products, little or no opportunity exists for public exposure during the manufacturing process.

### **End use**

As the formulated products are to be used for hair care both in hairdressing salons and domestically, widespread, direct, but intermittent, exposure of the public will occur. The extent of the public exposure will be dependent only on the commercial success of products containing the notified chemical and the duration of exposure will be determined primarily by the method of application, for which details have not been provided. The normal practice with hair care products of this type however, is to rinse them from the hair following a limited exposure period of generally less than half an hour.

## **8. ENVIRONMENTAL EXPOSURE**

### **Release**

Although the production activity takes place in a purpose constructed facility, some accidental release through spillage is possible during product formulation, and the notifier estimates that a maximum of 1% (annually 2 kg) of the imported volume may be lost in this manner. Similarly, during cleaning of the main batch tank and filling lines it is estimated that another 1% (2 kg per annum) of the new chemical may be lost. The material released in the plant as a result of spills and cleaning activities is sent with other waste to an on-site treatment facility consisting of a solids and oil interceptor followed by chemical/biological treatment. The effluent from this treatment is used for garden watering or recycled in the plant for other processing activities. The residual solids from the solids interception unit are presumably sent to landfill.

The notifier indicates that each empty drum is likely to contain 0.1 kg of the chemical, and consequently around 1 kg of the new chemical will be disposed of with the empty drums which are placed into landfill.

The notifier also estimates that around 2% of the hair care products are likely to remain in the

depleted consumer packages, and this would be discarded with household garbage which would be either placed into landfill or incinerated. This amounts to 2% of 195 kg, or roughly 4 kg per annum.

However, the new chemical is a component of cosmetic products, and the majority is consequently expected to be released into the environment through the sewage systems.

### **Fate**

The notifier provided a laboratory report on the assessment of the biodegradation of LC-2 conducted in accordance with the guidelines for the Modified OECD Screening Test [OECD TG 301E]. The results of this test provided indicated 66% loss of initial chemical oxygen demand (COD) of the LC-2 after 7 days, and 71% loss of COD after 28 days, which was interpreted in the report as indicating the material to be readily biodegradable under the conditions of this test. Strictly, the criteria for a compound to be classified as readily biodegradable under TG 301E is that greater than 70 % reduction in COD be attained after 28 days and that this level of degradation be achieved within 10 days of attainment of 10% degradation. Sodium benzoate which was used as the standard in this test had lost 97% of the initial COD after 28 days, but had been 70% degraded after only 4 days from start of the test.

Residual chemical disposed of to landfill in empty drums or with residual solids derived from water treatment at the production facility, would be subject to the biological and abiotic processes operative in these situations, and it is expected that the notified chemical would degrade to water, methane and carbon dioxide. Any waste material containing the notified polymer placed into compost facilities could also be expected to be destroyed through aerobic and anaerobic biological degradation processes. Similarly, incineration of the material would produce water vapour and oxides of carbon.

Most of the new chemical is expected to be released into sewerage systems, and the hydrophobic and surface active nature of the chemical ( $\log P_{ow} > 3.75$ , and estimated  $\log K_{oc} = 3.48$  - see above) indicates that it would become associated with the organic component of the particulate matter present in the raw sewage, and eventually become incorporated into sediments where it would be expected to undergo biological degradation.

Mackay Level 1 calculations (US Environment Protection Agency, 1998) indicate that when released to the environment the chemical would partition into the various environmental compartments as listed below:

<i>Soil compartment</i>	29.53%
<i>Sediment compartment</i>	27.56%
<i>Water compartment</i>	42.85%
<i>Aquatic biota compartment</i>	0.02%

Although the ASTER calculations also provide an estimate of 515 for the bioaccumulation factor for the compound in fish (fathead minnow), as it is relatively soluble in water and readily biodegradable the new chemical is not expected to bioaccumulate.

## 9. EVALUATION OF TOXICOLOGICAL DATA

### 9.1 Acute Toxicity

#### Summary of the acute toxicity of LC-2

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD <sub>50</sub> > 2 000 mg/kg	(Miyamoto, 1992a)
skin irritation	rabbit	slight to moderate irritant	(Tuffnell, 1992)
eye irritation	rabbit	slight to moderate irritant	(Miyamoto, 1992b)

#### 9.1.1 Oral Toxicity (Miyamoto, 1992a)

<i>Species/strain:</i>	rat/Sprague-Dawley
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	by gavage; vehicle: distilled water
<i>Clinical observations:</i>	all rats of both sexes exhibited decreased locomotion from 10 minutes after administration, and then crouching to pronation; recovery appeared from 1 hour; slightly decreased locomotion persisted in some animals up to 3 days after dosing; at 4 days after dosing, no abnormal appearance or behaviour was noted; body weight increases in all males and 3 out of 5 females were arrested until 4 days after dosing
<i>Mortality:</i>	none
<i>Morphological findings:</i>	none
<i>Test method:</i>	limit test similar to OECD TG401
<i>LD<sub>50</sub>:</i>	> 2 000 mg/kg
<i>Result:</i>	the notified chemical was of very low acute oral toxicity in rats

#### 9.1.2 Skin Irritation (Tuffnell, 1992)

<i>Species/strain:</i>	rabbit/New Zealand White
<i>Number/sex of animals:</i>	3/male



*Observation period:* 7 days

*Method of administration:* 0.5 mL in a single, 4-hour, semi-occluded application

*Draize\* scores (Draize, 1959):*

<b>Time after treatment (days)</b>	<b>Animal #</b>		
	<b>1</b>	<b>2</b>	<b>3</b>
<b><i>Erythema</i></b>			
1 hour	1	1	2
1	1	1	2
2	0	1	2
3	0	1	2
7	0	0 <sup>d</sup>	0 <sup>c</sup>
<b><i>Oedema</i></b>			
1 hour	1	2	2
1	0	1	2
2	0	1	2
3	0	0	1
7	0	0	0

\* see Attachment 1 for Draize scales; d = desquamation; c = crust formation

*Test method:* OECD guideline TG404 (Organisation for Economic Co-operation and Development, 1995-1996)

*Result:* the notified chemical was a slight to moderate skin irritant in rabbits

### 9.1.3 Eye Irritation (Miyamoto, 1992b)

*Species/strain:* rabbit/Japanese albino

*Number/sex of animals:* 3/female (eye irrigated group) and 6/female (eye unirrigated group) per test group

*Observation period:* 7 days

*Method of administration:* 100 mg of undiluted test substance or a 10% aqueous suspension into the conjunctival sac of the right eye; 30 seconds later the eyes of 3 rabbits

only per test group were flushed with 300 mL of warm water

*Results for undiluted test substance:*

*Draize scores (Draize, 1959) of unirrigated eyes:*

Time after instillation																						
Animal		Hours									Days											
		1	3	6	1	2	3	4	7													
Cornea		no scores above zero																				
Iris		no scores above zero																				
Conjunctiva		r	c	d	r	c	d	r	c	d	r	c	d	r	c	d	r	c	d			
1		2	0	1	2	0	0	2	0	0	1	0	0	all scores zero								
2		2	0	0	2	0	0	2	0	0	1	0	0									
3		2	0	1	2	0	1	2	0	0	1	0	0									
4		1	0	0	1	0	0	1	0	0	0	0	0									
5		1	1	1	1	1	1	1	1	1	1	0	0									
6		1	1	1	1	0	0	1	0	0	0	0	0									

<sup>1</sup> see Attachment 1 for Draize scales

o = opacity   a = area   r = redness   c = chemosis   d = discharge

*Draize scores (Draize, 1959) of irrigated eyes:*

	<i>Time after instillation</i>																	
<i>Animal</i>	<i>Hours</i>						<i>Days</i>											
	<i>1</i>	<i>3</i>	<i>6</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>7</i>										
<i>Cornea</i>	no scores above zero																	
<i>Iris</i>	no scores above zero																	
<i>Conjunctiva</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>
1	2	0	0	2	0	0	1	0	0	1	0	0	all scores zero					
2	1	0	0	1	0	0	0	0	0	0	0	0						
3	1	0	0	1	0	0	0	0	0	0	0	0						

<sup>1</sup> see Attachment 1 for Draize scales

o = opacity   a = area   r = redness   c = chemosis   d = discharge

*Irrigated eyes:*

irrigation was palliative

*Results with 10% aqueous suspension:*

no corneal or iridal effects; no conjunctival chemosis; slight conjunctival redness in all animals from 1 hour to: 1 day in 4 animals, 6 hours in 1

animal and 3 hours in 2 animals; slight discharge in 4 animals at 1 hour

*Test method:* unspecified

*Result:* the undiluted notified chemical was a slight to moderate eye irritant in rabbits; a 10% aqueous suspension of the notified chemical was a slight eye irritant in rabbits

## 9.2 Genotoxicity

### 9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (Jones, 1993)

*Strains:* TA 1535, TA 1537, TA 1538, TA 98, TA 100

*Concentration range:* 0, 50, 150, 500, 1 500, 5 000 µg/plate

*Test method:* OECD guideline TG471 (Organisation for Economic Co-operation and Development, 1995-1996)

*Result:* negative controls were within acceptable limits and the concurrent positive controls demonstrated the required sensitivity of the assay; no evidence of toxicity was observed at the top dose as judged by a lack of effect on the number of spontaneous mutant colonies appearing after treatment and plating

the notified chemical did not induce mutations in any of the strains tested in either the absence or the presence of metabolic activation provided by Arochlor-1254 induced rat liver S9 fraction

## 9.3 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity in rats ( $LD_{50} > 2\,000$  mg/kg), was a slight to moderate skin irritant and eye irritant in rabbits and was not mutagenic in *Salmonella typhimurium*.

On the limited data available the notified chemical would not be determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although not required by the Act for new chemicals imported in annual quantities less than one tonne, the notifier supplied the following ecotoxicity data - specifically laboratory reports on the acute toxicity of LC-2 to rainbow trout and on the immobilisation of *Daphnia magna*.

<i>Test</i>	<i>Species</i>	<i>Results (Nominal)</i>
Acute Toxicity [OECD 203]	<i>Oncorhynchus mykiss</i> (Rainbow trout)	LC <sub>50</sub> (96 h) = 10 mg/L NOEC (96 h) = 3.1 mg/L
Acute Immobilisation [OECD 202]	<i>Daphnia magna</i>	EC <sub>50</sub> (48 h) = 0.12 mg/L NOEC(48h) = 0.056 mg/L

The ecotoxicity tests were performed in accordance with OECD Test Guidelines. The Stock “solutions” of the new chemical were prepared by dispersing a known weight of LC-2 in dechlorinated tap water using an ultrasonic disrupter, then successively diluting this stock to prepare the range of solutions used in the tests.

The tests on rainbow trout were performed using solutions of the test material in a semi-static (renewal) system over a 96-hour period at 14°C. The water was removed daily and replaced with fresh water containing the respective concentrations of the test material. Six solutions of the chemical with concentrations of 3.12, 6.25, 12.5, 25, 50 and 100 mg/L were tested, together with one control. The highest test concentration of 100 mg/L is larger than the reported water solubility of 74 mg/L, but the test report did not indicate that this solution was cloudy or make other mention of problems with solubility.

Ten fish were tested at each concentration, and the test solutions were analysed for their content of LC-2 by chromatography before and after each test. The analytical results were always within 3% of the nominal concentrations.

The tests results indicate that the material LC-2 is moderately toxic to the rainbow trout with a 48 hour LC<sub>50</sub> of 10 mg/L using the moving average method of Thompson (Thompson, 1947). Probit analysis on the raw data confirmed this result. Sublethal effects observed in the fish were lethargy and swimming on the bottom of the test vessels.

The acute immobilisation tests on *Daphnia* were performed in a static test over a 48-hour test period at 22°C with nominal solution concentrations of the notified substance of 0.01, 0.018, 0.032, 0.056, 0.10, 0.18, 0.32, 0.56, and 1.0 mg/L, together with one control containing no test material. Direct analytical confirmation of LC-2 concentrations in the test solutions was not possible since the nominal concentrations were always below the detection limits of the available equipment.

During these tests the pH of the test solutions was always between 7.8 and 7.9, while dissolved oxygen levels were always between 7.9 and 8.2 mg/L. The tests were performed in duplicate using 10 animals for each test. The 48 hour LC<sub>50</sub> loading (nominal) was determined as 0.12 mg/L using the moving average method of Thompson (Thompson, 1947), and confirmed by Probit analysis on the raw data. The results indicate that the chemical is highly toxic to this species.

The QSAR calculations of the ASTER database (US Environment Protection Agency, 1998) also furnished predictions for acute toxicity to rainbow trout and to Daphnia, which are compared with the experimental data below.

	<i>ASTER Estimate</i>	<i>Experimental Data</i>
<i>Oncorhynchus mykiss</i> (Rainbow trout)	LC <sub>50</sub> = 3.07 mg/L	LC <sub>50</sub> = 10 mg/L
<i>Daphnia magna</i> (Water flea)	LC <sub>50</sub> = 4.87 mg/L	LC <sub>50</sub> = 0.12 mg/L

While the calculated LC<sub>50</sub> for rainbow trout is in reasonable accord with the experimental data, the calculated LC<sub>50</sub> for Daphnia significantly underestimates the toxicity of LC-2 to this species. Calculated acute toxicity data are also available for three other fish species (range of LC<sub>50</sub> is 3.4 to 8 mg/L), and also for Fathead minnow calculated chronic toxicity data which provided an estimated Maximum Acceptable Tolerable Concentration (MATC) (32 d) of 1.1 mg/L.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the new chemical is an ingredient of cosmetic formulations and most of the material would eventually be released into domestic sewage systems as a consequence of product use. The notifier provided some estimates of the Predicted Environmental Concentrations (PEC) resulting from use of the hair straightener product (containing 0.2% of LC-2), which indicate that the maximum possible concentration of the new chemical in receiving waters derived from large metropolitan sewage catchments would be 0.0082 mg/L, while in rural areas the corresponding concentrations would be around 0.2 mg/L.

The basis of these calculations assumes the entire contents of a 250 mL bottle of hair straightener (containing 0.5 g of LC-2) is washed into the sewer with 60 L of shower water, which is then diluted in the sewer (1:10 in metropolitan areas and 1:2 in rural areas). Further dilution occurs in the sewage treatment plants (again by factors of 1:10 in metropolitan areas and 1:2 in rural areas), with a final dilution of 1:10 in the receiving waters.

As indicated above, both these PEC calculations are based on the premise that the entire contents of a single consumer pack of 250 mL (containing 0.2% of the new chemical) are washed into sewer at one time, whereas in fact the notifier indicates that usually only around 8% of the contents of the package would be used at any one time. Further, no allowance for some of the chemical remaining adsorbed to hair was made in these estimates. Given these considerations, it is likely that PECs of around 1/10 of those given above would be more realistic - ie 0.0008 mg/L for metropolitan catchments and 0.02 mg/L in rural areas.

However, the hair conditioner product contains around 1% of the new chemical, and using the same calculation methodology as outlined above, the PECs of LC-2 resulting from use of this would be 0.004-0.04 mg/L in metropolitan catchments, and 0.1-1.0 mg/L in rural situations.

These calculations may have underestimated the probable dilution factors, and consequently

these PECs may be too high. Based on 100% discharge of the new chemical into Australian domestic sewers (ie 200 kg per year, or 550 g per day), and assuming an average of 150 L of water released to sewer per person per day with a national population of 18,000,000, the average nationwide PEC in sewage treatment plant effluent is 0.0002 mg/L.

The ecotoxicity data indicates that the new chemical is toxic to aquatic species, and particularly so for invertebrates (eg – for *Daphnia* where the  $LC_{50} = 0.12$  mg/L). When released into the environment via sewage discharges during the normal processes associated with usage of hair care product containing LC-2, the mean predicted environmental concentration in receiving waters on a nationwide basis is well below this  $LC_{50}$ . However, the worst case calculations provided by the notifier indicate a possible environmental hazard associated with the use of hair care products containing the new chemical in country areas where domestic water usage may be constrained during periods of drought.

However, the chemical is relatively hydrophobic with  $\text{Log } P_{ow} > 3.75$ , and the Mackay Level 1 calculations mentioned above indicate that once released to sewer systems and final receiving waters, much of the chemical would become adsorbed into the organic component of particulate matter in these waterways, and eventually become associated with aquatic sediments. This mechanism would operate to decrease the potential for its exposure to aquatic organisms, and since the new chemical is readily biodegradable it is expected that it would be decomposed within the aquatic system, and that overall environmental concentrations would be unlikely to increase with prolonged release of the chemical to waterways.

The above considerations indicate minimal hazard to the environment when products containing the new chemical are used in large metropolitan centres where dilution of sewage effluent is expected to be large. However, in rural areas where dilution factors may be considerably smaller, the available ecotoxicity data indicates some potential risk to aquatic systems, particularly for those containing low concentrations of suspended matter.

## **12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS**

On the basis of limited toxicological data, the notified chemical is not shown to be acutely toxic or genotoxic. However, it is a slight to moderate skin irritant and eye irritant. Nothing is known of the effects after repeated or prolonged exposure or skin sensitising effects. The notified chemical would not be determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a) in terms of the submitted toxicological data.

The risk of adverse health effects to waterside workers, transport workers or warehouse workers is expected to be minimal except in the case of accidental spillage.

During the formulation and retail packaging process, the sole operation where there is a risk of adverse health effects is in removal of the chemical from the 20 kg plastic containers in which it is to be imported and its transfer to the enclosed, flameproof mixing vessel in which hair care products are formulated. The notifier states that chemical safety glasses and gloves are worn during these procedures which will serve to minimise the risk of skin or eye irritancy identified as the main hazards of the chemical. This protection will also serve to

minimise the risk of effects after repeated or prolonged exposure and sensitising effects for which the toxicological data are lacking. Following addition of the notified chemical to the mixing vessel, the system of mixing and package filling is automated and enclosed. In addition, the concentration of the notified chemical in the final products is not greater than 1% so that the risk of adverse health effects following addition of the chemical to the mixing vessel is negligible.

Workers in hair dressing salons will experience frequent skin contact with the notified chemical. Approximately 25% of the notified chemical compounded into hair conditioner will be used in hair salons. This may involve exposure of the hands of hairdressers for approximately 1 hour per day for 230 days per year. Due to the low concentration of the notified chemical in the hair conditioner, the risk of adverse health effects such as skin irritation to salon workers should be low, however the possibility of skin sensitisation cannot be excluded.

Although public exposure is likely to be widespread the chemical characteristics of the notified chemical and its toxicity profile indicate that the acute hazards are confined to self limiting skin and eye irritation. At 0.2 to 1% of the end use formulation the hazards identified for the notified chemical are likely to be substantially attenuated and the wash off nature of the end use products will constrain the exposure period. Based on the toxicity data, the proposed concentration and the use pattern of the notified chemical, the risk to the public from exposure to this compound as an ingredient in hair care products is considered to be low.

### **13. MATERIAL SAFETY DATA SHEET**

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

### **14. RECOMMENDATIONS**

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987);
- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillage should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

## 15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed. If annual quantities of the new chemical are anticipated to rise above 1 000 kg, the notifier will be required to provide the full set of physico-chemical test reports, together with reports on Daphnia reproduction and the toxicity of the new chemical to algae.

## 16. REFERENCES

Draize JH (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.

Jones E (1993) LC-2: Bacterial Mutation Assay, Project No. KSP 240B/930231, Safepharm Laboratories Limited, Derby, U.K.

Miyamoto K (1992a) The Acute Oral Toxicity of Isostearyl Pentaerythryl Glyceryl Ether (LC-2) in Rats, Project No. 9122-1, Saitama Institute Drug Safety Testing Center Co., Ltd, Hiki, Saitama, Japan.

Miyamoto K (1992b) A Test for Eye-Mucosal Irritancy of Isostearyl Pentaerythryl Glyceryl Ether (LC-2) in Rabbits, Project No. 9122-7, Saitama Institute Drug Safety Testing Center Co., Ltd, Hiki, Saitama, Japan.

National Occupational Health and Safety Commission (1994a) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.



National Occupational Health and Safety Commission (1994b) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

Organisation for Economic Co-operation and Development (1995-1996) OECD Guidelines for the Testing of Chemicals on CD-Rom. OECD, Paris.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Standards Association of Australia, Sydney.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia, Sydney.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2-1998, Occupational protective gloves, Part 2: General requirements. Standards Association of Australia, Sydney.

Thompson WR (1947) The use of Moving Averages and Interpolation to Estimate Median Effective Dose. Bact. Rev., 11 : 115-145.

Tuffnell PP (1992) LC-2: Acute Dermal Irritation Test in the Rabbit, Project No. 140/210, Safepharm Laboratories Limited, Derby, U.K.

US Environment Protection Agency (1998) ASTER Ecotoxicity Profile: 1-O-octadecyl-3-O-[2-tris (hydroxymethyl) ethyl] glycerol - [CAS No 14692-83-9], Project No. United States Environmental Protection Agency, Office of Research and Development, National Health and Environmental Effects Research Laboratory, Mid-Continent Ecology Division.

## Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

<i>Erythema Formation</i>	<i>Rating</i>	<i>Oedema Formation</i>	<i>Rating</i>
No erythema	0	No oedema	0
perceptible)	1	Very slight erythema (barely perceptible)	1
Well-defined erythema	2	Very slight oedema (barely perceptible)	1
Moderate to severe erythema	3	Slight oedema (edges of area well-defined by definite raising)	2
Severe erythema (beet redness)	4	Moderate oedema (raised approx. 1 mm)	3
		Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

### *CORNEA*

<i>Opacity</i>	<i>Rating</i>	<i>Area of Cornea involved</i>	<i>Rating</i>
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

### *CONJUNCTIVAE*

<i>Redness</i>	<i>Rating</i>	<i>Chemosis</i>	<i>Rating</i>	<i>Discharge</i>	<i>Rating</i>
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

### *IRIS*

<i>Values</i>	<i>Rating</i>
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe