File No: STD/1047

June 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

MIPA-Laureth sulfate

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Beiersdorf Australia Ltd (ABN 98 000 025 623), 4 Khartoum Rd, North Ryde NSW 2113.

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: concentration of the notified chemical in the imported product.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: toxicity data are not available for the notified chemical but there are adequate data on analogue chemicals. Physicochemical data are largely unavailable. However, the physicochemical properties of the notified chemical are expected to be similar to similar surfactants.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
2-Propanol, 1-amino-, compd. with α-sulfo-ω-(dodecyloxy)poly(oxy-1,2-ethanediyl) (1:1)

OTHER NAME(S)
MIPA-Laureth sulfate.

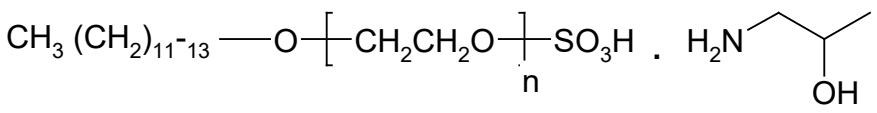
MARKETING NAME(S)
MIPA-Laureth sulfate in Zetesol 100, Zetesol 856 or Zetesol 856 D

Nivea Bath Care Pampering Shower Oil (finished product containing notified chemical)

CAS NUMBER
83016-76-6

MOLECULAR FORMULA
$C_3H_9NO.(C_2H_4O)_n.C_{12}H_{26}O_4S$

STRUCTURAL FORMULA



Where n = 1-4

MOLECULAR WEIGHT
384 g/mol (calculated on the basis of the average MW of fatty alcohol for n = 1)

SPECTRAL DATA

ANALYTICAL METHOD	Infrared (IR) spectroscopy
Remarks	Major absorbance 3419, 3097, 2919, 2855, 1646, 1538, 1462, 1231, 1215, 1123, 1062, 1023, 923, 785 cm^{-1}.
Test Facility	Zschimmer & Schwarz GmbH &Co kg

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	IR spectroscopy

3. COMPOSITION

DEGREE OF PURITY
99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None present at levels above the cutoff for classification of the notified chemical as a hazardous substance..

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

ADDITIVES/ADJUVANTS

The imported product contains the notified chemical at < 50%.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
There will be no local manufacture of products containing the notified chemical. The product will be imported as fully finished and will be transported and stored in the original container. The product will be imported in a 200 mL plastic bottle, shrink-wrapped into sixes and packed in cardboard cartons. The product is not Dangerous Goods and no special transport containers are required. The main operations will be warehousing and transport. The products will be sold to retail outlets such as department stores and pharmacies.

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

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

USE
Anionic surfactant in shower oil.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Notifier.

TRANSPORTATION AND PACKAGING
In 200 mL plastic bottles packed into cardboard cartons.

5.2. Operation Description

Transport workers will unload shipping containers and load them onto trucks for road transport from the dockside in Sydney to the Beiersdorf warehouse and distribution centre at Huntingwood, NSW. The product will be stored and distributed to either other warehouses interstate belonging to the applicant or directly to customer warehouse facilities. At the warehouses, forklift drivers will move pallets of product to and from storage shelving. Workers (pickers) may also open shipping cartons and re-pack them with other goods to fill smaller orders.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Storage	6-10	1-2	50
Retail	> 5000	0.5 - 1	230

Exposure Details

Exposure will only occur in the unlikely event of an accident where the containers are damaged and product is spilt.

At the retail outlets, workers will remove the products from shipping cartons and place the products on shelves for sale. These workers may also be involved in the clean up of minor spills from damaged containers.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical in the shower oil will be imported as a fully finished product to be sold at retail outlets in the original containers.

RELEASE OF CHEMICAL FROM USE
Practically all of the notified chemical will be released to sewer during use of the shower oil when washed from the body. A small amount may be disposed of in landfill when the empty containers are discarded. The notifier estimates 4750 kg of notified chemical will be released to sewer, while the remaining 250 kg residues in containers will go to landfill.

5.5. Disposal

The notified chemical will be disposed of to sewer or in landfill by domestic garbage collection.

5.6. Public exposure

The notified chemical will be imported in a cosmetic product and used as a shower oil. The product will be used by the public and will be applied to the hair and body. The notified chemical will be used at a concentration of < 50% and, if 30 g of product is applied to the skin, then the exposure will be to a maximum of 15 g of the notified chemical with each application and a dose of 250 mg/kg body weight. However, the product will be in contact with the skin for only a short period before it is rinsed off and is unlikely to be absorbed across the skin to a significant degree. The product is likely to be used once per day. Consumers will be advised to stop application of the product if any skin reactions occur.

6. PHYSICAL AND CHEMICAL PROPERTIES

No data are available for the notified chemical. However, the physicochemical properties are expected to be similar to sodium and ammonium laureth sulfates (Moore, 1983). These are free-flowing, clear liquids whose viscosity varies from a few hundred to several thousand centipoises. The sodium salt is soluble in water and alcohol whereas the ammonium salt is soluble in water but insoluble in oils, fats and waxes. The approximate melting point of the sodium salt is 126-136°C. The pH of 10% aqueous solutions is approximately 7.5–9 for the sodium salt, and 6–7 for the ammonium salt. The water/octanol partition coefficient and water solubility can not be determined for surfactants. The notified chemical is not expected to have a significant vapour pressure since it is an organic salt. Due to the low vapour pressure, the notified chemical is not expected to be flammable.

The notified chemical is the salt of a strong acid and a weak base. The anion should remain dissociated in the aqueous environment. It should not hydrolyse but despite its high water solubility may sorb to soils and sediments due to its surface activity. 1-amino-2-propanol (MIPA) has a pKa for the protonated form of ~ 9.5 (based on 2-aminoethanol – CRC Handbook) and will be mostly protonated (cationic) over most of the environmental pH range.

7. TOXICOLOGICAL INVESTIGATIONS

There is only one toxicological study available for either the pure substance or a product containing it. That is a skin irritancy study for Zetesol 100 containing > 10% notified chemical. The toxicological profile of the notified chemical can be ascertained from studies on analogues.

7.1. Toxicity of a product containing the notified chemical

7.1.1 Skin irritation

TEST SUBSTANCE 3% Zetesol 100 (contains > 10% notified chemical).

METHOD Safepharm standard protocol GM 09/80/04A.
Species/Strain Rabbit/New Zealand White
Number of Animals 6
Vehicle Distilled water.
Observation Period 72 hours.
Type of Dressing Semi-occlusive.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.8	2	72 hours	1
Oedema	0.5	1	72 hours	1

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

CONCLUSION 3% Zetesol 100 is slightly irritating to skin.

TEST FACILITY Safepharm (1982).

7.2. Published information on constituents of the notified chemical

7.2.1 MIPA

Excerpts from the Hazardous Substances Data Bank (Tomes Plus) suggest that Isopropanolamine is a severe eye irritant and of low acute oral toxicity (LD50 4.26 g/kg). It is stated to be toxic via inhalation and dermal contact.

7.2.2 Sodium and ammonium laureth sulfates

A safety assessment on the closely related chemicals sodium laureth sulfate and ammonium laureth sulfate has been published as a Cosmetic Ingredient Review (1983). The review concentrates on species with an average degree of ethoxylation of 1 to 4, similar to the notified chemical. A summary of the conclusions follows.

Acute oral toxicity

Sodium laureth sulfate: The acute oral toxicity (LD50) in albino rats was 3.2 or 3.38 mL/kg where a range of dosages was administered in two studies. Another study gives a value of > 2.9 g/kg. Other studies are less conclusive, although in one study with Wistar rats 3/10 rats died at a dosage of 1.25 mL/kg. On balance it seems likely that sodium laureth sulfate is of low acute oral toxicity in rats. Effects at and around the LD50 were lethargy and diarrhea.

Ammonium laureth sulfate: Although in one study the LD50 was < 0.63 mL/kg and 7/10 albino rats died, two larger studies were done with 50 Sprague-Dawley rats and doses of 1 – 100 g/kg of a test solution of either 26 or 27% concentration. Less than 50% of the rats died (5/50 and 12/50) and the LD50s were accordingly

calculated at 1.7 or 3.25 g/kg. At dosage levels of 12.1 – 14 g/kg, all animals that died showed reddened lungs, livers, stomachs, intestines and kidneys.

Acute dermal toxicity

A single study in rabbits using ammonium laureth sulfate was at a dosage of 0.01 g/kg, with no mortality.

Dermal irritation

Sodium laureth sulfate: A large number of studies were performed with a variety of concentrations under occlusive patch for 24 – 48 hours. Applications produced no irritation at 5 – 5.6%, mild erythema and oedema at 6 – 10%, 17.5% and 26%. Severe irritation occurred at 15, 25, 28 and 30%. Severe irritation was produced in 3 applications of a 15% solution on consecutive days but similar studies with 17.5% produced only mild irritation. Single applications of 26 and 28% produced mild and moderate irritation, respectively, and an application of 58% produced no irritation. Three studies using 30% applications for 3 days produced severe irritation. Effects on the skin and hair cycles were investigated by application of the chemical daily for 65 days. A 60% concentration caused inflammatory changes, epidermal hyperplasia, epidermoid cyst formation and diffuse hair loss. A 30% concentration caused similar but less severe changes and 9% caused no changes.

Ammonium laureth sulfate: A large number of studies on albino rabbits suggested that 7.5% was slightly irritating, 12 – 15% moderately irritating and 25 – 60% severely irritating.

Eye irritation

Sodium laureth sulfate: Eye irritation in albino rabbits using 1.3 – 58% ranged from no irritation to severe eye damage with no dose dependency.

Ammonium laureth sulfate: A concentration of 7.5% produced slight irritation rising to severe irritation in a dose-dependent manner at 60%.

Skin sensitisation

A 0.1% aqueous solution was applied topically to 10 guinea pigs 3 times a week for 3 weeks. It caused no skin sensitisation when challenged topically 10 days after the final weekly application. However, animals challenged by intradermal injections showed a “blistering” effect one hour after challenge. At 24 hours positive reactions were seen in all animals and at 48 hours 6/10 animals showed a definite positive reaction.

Subchronic and Chronic toxicity

Sodium laureth sulfate: No observed effect levels were 1000 ppm in the diet of rats in a 13-week subchronic study and 5000 ppm in a 2-year study in relation to gross or microscopic effects. In the 13-week study, sodium laureth sulfate was fed to groups of Carnworth Farm “E” rats (12/sex) at 40, 200, 1000 or 5000 ppm. Rats fed 5000 ppm had increased absolute kidney weights in males and absolute heart, liver and kidney weights in females but there were no changes in relative organ weights.

Ammonium laureth sulfate induced moderate to severe skin inflammation in a repeated dose 28-day dermal study in rabbits when treated for the first time with 200 mg/kg and then 50 mg/kg subsequently.

Other studies

Sodium laureth sulfate at 0.1% in the diet of male and female rats for 14 weeks had no effect on fertility, litter size, lactation or survival of offspring. The first generation were maintained on the same diet as their parents and mated when 100 days old. Their offspring were kept on the same diet for 5 weeks. No changes in haematology, urinalysis occurred and there were no macroscopic or microscopic findings.

A 5% aqueous solution applied twice weekly to female Swiss mice for 105 weeks was not tumourigenic. A 0.28% solution was not irritating to the vaginal mucosa of beagles but a 28% solution produced redness.

Ammonium laureth sulfate at 0.11% did not induce vaginal irritation in beagles treated 5 days a week.

Clinical studies

An 18% solution of sodium laureth sulfate produced a low level of irritation in 3 of 20 subjects but a second 18% solution induced mild irritation in 11 of 20 subjects when applied under a 24-hour occlusive patch. No primary irritation or sensitisation was produced in 196 subjects treated with 0.5% solution. A 21-day subchronic dermal study showed a 1.25% solution to be highly irritating while another study utilising a 0.07% solution indicated a moderate potential for mild cumulative irritation in the four subjects who completed the study. A formulation containing 14.3% sodium laureth sulfate caused no contact sensitisation when applied to the same site on the volar forearm or back of all subjects for 5 alternate day 48-hour periods. The patch site was pretreated with 2.5% aqueous sodium lauryl sulfate for 24 hours. After a 10-day rest period, a challenge patch (occluded) was applied to a different site for a 48-hour period. Prior to challenge, 5 - 10% sodium lauryl sulfate was applied to the test site for one hour. A formulation containing 0.07% of the chemical when tested for phototoxicity caused a weak, nonvesicular reaction in 4 of 103 subjects. A similar test produced a mild reaction of unspecified type in 2 of 56 subjects.

Ammonium laureth sulfate: Irritant contact dermatitis was produced during a standard repeated insult patch test using 0.29% for induction and 0.15% for challenge. During induction, one third of subjects had mild to moderate irritation. A similar conclusion was reached when 0.115% was tested in a formulation, and also 0.23%. Phototoxicity was tested with a product containing 0.11% ammonium laureth sulfate by 5 consecutive occlusive daily patches on the arms which were then exposed to direct sunlight for 30 minutes. Moderate skin irritation was seen on 6 panellists but the reactions were judged not to be phototoxic. Two products containing 0.11% ammonium laureth sulfate were used in a cumulative sensitivity test where 21 daily occluded applications were given. It was concluded the products showed evidence of having moderate potential for mild cumulative irritation under continued reapplication and occlusion. Ocular irritation was tested on 0.9 – 1.8% “ammonium alcohol ethoxy sulfate” where alkyl change length and degree of ethoxylation were unknown. It was non-irritating when instilled into the eyes of 20 human volunteers. When applied once daily for 2 weeks to male and female genitalia, 2.25% “ammonium alcohol ethoxy sulfate” was non-irritating.

7.3. Published information on other related compounds

7.3.1 Alkyl ether sulfates

The Danish Environmental Protection Agency has reviewed the impacts of alkyl ether sulfates (AES) on human health and the environment.

The general structure of alkyl ether sulfates is:

$C_{10-14}CH_2CH_2O(CH_2CH_2O)_{1-4}—SO_3^-Na^+$

This category includes the laureth sulfates.

The LD50 values after oral administration of AES range from 1 – 5 g/kg bw for rats indicating low acute oral toxicity.

AES are easily absorbed in the intestine of rats and humans after oral administration. $C_{11}AE_3S$ and $C_{12}AE_3S$ are extensively metabolised and eliminated in rats. Only small amounts of non-specified AES were shown to be absorbed via the skin.

Moderate to strong irritation can be expected at concentrations of 10% or above but only mild to slight irritation was observed at 1% of a non-specified AES.

A 90-day subchronic feeding study in rats with 1% AE_3S or AE_6S with alkyl chain lengths of C_{12-14} showed only an increased liver to body weight ratio. In 2-year chronic toxicity studies in rats 0.5% in the diet or drinking water sometimes resulted in increased kidney or liver weights but doses up to 0.05% of C_{12}-AE_3S had no effect.

Carcinogenic effects of oral ingestion or skin application of AES were not apparent.

Reproductive or teratogenic effects of a mixture (55:45) of AES and linear alkyl benzene sulfonates were not seen in a two generation rat feeding study. No changes in reproductive or embryogenic parameters were observed in rats administered dietary levels of 0.1, 0.5 or 1%.

7.3.2 Sodium lauryl sulfate (SLS) and ammonium lauryl sulfate (ALS)

A safety assessment on the analogues sodium and ammonium lauryl sulfate was published in 1983 (J Am Coll Toxicol, 1983) and a summary follows:

The molecular formula of sodium or ammonium lauryl sulfate is:

$CH_3(CH_2)_{10}CH_2OSO_3Na$ (or NH_4)

While the alkyl sulfates, as a class, generally show higher irritancy that the alkyl ether sulfates such as the notified chemical (Madsen *et al.*, 2001) they are nonetheless acceptable analogues for other effects, particularly where surfactant properties are involved.

SLS shows degenerative effects on cell membranes due to protein denaturation in absorption, metabolism and excretion studies. The acute oral LD50 in Wistar rats ranged from 0.8 to 1.1 g/kg body weight when SLS was administered as a 10% solution. In Sprague-Dawley rats, the acute oral LD50 of SLS administered as a 28.2% solution was 6.0 g/kg with pulmonary haemorrhage the major cause of death at necropsy. In Carnworth Farm E rats the acute oral LD50 of SLS administered at 25% (w/v) in distilled water was 1.29 g/kg. In another study the acute oral LD50 of SLS was found to be 1.65 g/kg. Signs of intoxication included diuresis, diarrhoea, lacrimation, salivation, tremors, convulsions, sedation, anaesthesia and death. Dead rats had hyperaemia of the liver and kidneys. In two other studies the acute oral LD50 in rats of a 21% solution of SLS was calculated as 3.10 and 2.71 g/kg.

For ALS administered as a 27.4% solution, the acute oral LD50 was 4.7 mL/kg with pulmonary haemorrhage the cause of death. The acute oral LD50 of a shampoo containing 15% ALS was 8 – 9 mL/kg.

The acute dermal toxicity of 26% SLS in a shampoo was greater than 10 mL/kg in albino rabbits. Signs of systemic toxicity were depression, laboured respiration, abnormal positions of hind legs and nasal discharge.

Subchronic oral repeat dose studies were conducted in rats with SLS. A 13-week feeding study used 40, 200, 1000 and 5000 ppm active material. The only significant finding was an increase in absolute organ weights and 5000 ppm and increased hepatic weights occurred in females of the 5000 ppm group. The no effect dietary level was 1000 ppm. Weanling male rats fed drinking water containing 0%, 0.05% or 0.25% SLS for 5 months had increased lung and kidney weights at the high concentration.

Chronic toxicity studies with SLS and ALS did not show any systemic toxicity. Osborne Mendel rats were fed SLS in the diet at 0.25%, 0.5% and 1% for 2 years whereas with ALS a product containing 17.5% was diluted 1/10 and applied to the skin for 91 days. Beagle pups received 0%, 0.67%, 1.0% and 2.0% SLS in the diet for 1 year and no systemic effects were observed.

A 1-year chronic oral toxicity study using beagles showed that 2% SLS in the diet was not tumourigenic or carcinogenic.

Rats fed 0.56% and 1.13% SLS for 90 days did not exhibit clastogenic effects.

A teratogenicity study in JCL/ACR mice employed daily dermal applications of 0.4%, 4.0% and 6.0% aqueous SLS on days 6 – 13 of pregnancy. There was a reduction in maternal weight and growth rate with application and the rate of pregnancies brought to term was low for mice in the high concentration group. Delayed ossification occurred and foetal weight and growth were retarded in the 4% and 6% treated groups.

SLS and ALS were tested in human skin irritation studies and irritation increased with concentration up to 10%. Open patches were less irritating than closed patches and similar results were obtained for formulated products. No UV sensitisation was observed with formulations containing 0.21% - 2.5% SLS and 0.11% - 1.68% ALS.

8. ENVIRONMENT

8.1. Environmental fate

Biodegradation
No environmental fate data were provided for the notified chemical. An environmental assessment report has been published by the Danish EPA (Masden *et al*, 2001), which contains information on analogue alkyl ether sulfates (AES) of chain lengths C_{10-14}, which are very similar in structure to the notified chemical (chain lengths C_{10-13}), apart from having different salt species attached, and are expected to behave in similar ways in the environment.

AES is readily biodegradable under aerobic conditions. Biodegradation is greater for linear primary AES (as is the case here) than for branched tetra-propylene primary AES. In OECD TG 301 tests, rapid primary degradation of 70-100% in 1 to 5 days is reported for AES of chain length C_{12-14}. Biodegradation occurs through cleavage of the ether bond, which may take place at any ether bond. Cleavage produces a fatty alcohol or an alcohol ethoxylate, and ethylene glycol sulfates of various lengths (Madsen *et al* 2001). The alcohol is subsequently degraded by oxidation, whereas the ethylene glycol sulfate is eliminated stepwise by oxidation, cleavage of C2-units, and desulfation.

AES is readily biodegraded under anaerobic conditions, with tests showing 64% removal in 28 days for C_{12-14} chain lengths. In ultimate anaerobic tests with digester sludge (24-29 g/L medium), 88% was degraded after 17 days incubation at 35°C. Anaerobic biodegradation pathways have not been verified.

Bioaccumulation
The uptake, distribution and elimination of ^{35}S labelled C_{12} AE_3S and $C_{12}AE_5S$ have been investigated in Carp (*Cyprinus carpio*). The following BCF values for the two substances respectively were determined: Whole body, 18 and 4.7; gall bladder, 3400 and 940; and hepatopancreas, 46 and 18. Both uptake and elimination were reported to be rapid. The high concentrations found in the gall bladder were thought to be due to biotransformation of AES in the liver and subsequent excretion of radiolabelled metabolites in the gall bladder. Due to metabolism in organisms, it was thought that the BCF values were overestimated. For the whole body, and the gall bladder, steady state was not reached within 72 hours, hence the reported values are considered to be invalid. Masden *et al* (2001) concluded that AES is not considered to bioconcentrate in aquatic organisms.

8.2. Ecotoxicological investigations

No ecotoxicological data were provided for the notified chemical. An environmental assessment report has been published by the Danish EPA (Masden *et al,* 2001), which contains a number of toxicity endpoints for analogue alkyl ether sulfates. The information is summarised below.

Fish
The 24-96 h LC50 values for seven different fish species range between 0.39 mg/L to 450 mg/L. The toxicity of AES with chain length $<C_{16}$ decreases with increasing numbers of EO groups and peaks at chain lengths of C_{16}. For example, in a study with bluegill sunfish (*Lepomis macroshirus*) exposed to AES (C_8 to $C_{19.6}$ and 1-3 EO), the LC50 values were >250 mg/L for C_8 and 375 mg/L for C_{10}, with values decreasing to 24 mg/L for C_{13}, 4-7 for C_{14}, 2 mg/L for C_{15}, and 0.3 mg/L for C_{16}. For chain length > $C_{17,}$ the LC50s increase again to 10.8 mg/L.

Invertebrates
For *Daphnia magna*, the acute EC50 values range between 1 and 50 mg/L. Endpoints reported for $C_{13.67}$ $AE_{2.25}S$, include a 96 h LC50 of 1.17 mg/L, a 21 d LC50 of 0.74 mg/L, an NOEC of 0.27 mg/L, and a 21 d LC50 for reproduction of 0.37 mg/L. In a mesocosm study with C_{14-15} $AES_{2.17}S$, the LOEC for invertebrate communities was 0.77 mg/L and the NOEC was 0.25 mg/L.

Algae
For algae, typical EC50 values range from 4 to 65 mg/L. For AES with chain lengths in the same range as the notified chemical, the 21 day EC50 is 20 mg/L for C_{12-14} AE_nS, the 72 h EC50 is 32 mg/L for C_{12-14} AES and the 48 h EC50 is 65 mg/L for C_{10-15} AE_3S.

Isopropanolamine

Ecotoxicological endpoints for the counter ion, isopropanolamine, are available in Verschueren (1996), and indicate an NOEC for *Pseudomonas putida* of 5000 mg/L, a 72 h EC50 for *Scenedesmus subspicatus* of 23 mg/L, a 48 h EC50 for *Daphnia magna* of 108.8 mg/L, and a 96 h LC50 for goldfish of 210 mg/L.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

It is estimated 4750 kg of the notified chemical contained in shower oil will be released to sewer when it is washed from the body during showering, a further 250 kg residues will go to landfill.

A daily PEC in the sewer was calculated assuming 4750 kg of the import volume is discharged each year in a diffuse manner with no attenuation within the sewage systems. Based on dilution factors of 0 and 10 for inland and ocean discharges of STP-treated effluents, the predicted daily PEC of the notified chemical in fresh water is approximately 3.3 X 10^{-3} mg/L and in marine surface waters, approximately 3.3 X 10^{-4} mg/L. The calculations assume an Australian population of 19.5 million people and an average value for water consumption of 200 L/person/day (3900 ML/day for total population).

Initially, the notified chemical is expected to partition predominantly in the water compartment, unless ionized, when it should partition to sediment. AES is readily biodegradable under aerobic and anaerobic conditions, and is expected to readily degrade within a time frame of days to a week. The counter ion, isopropanolamine, is also biodegradable according to data in Verschueren (1996), showing a % theoretical oxygen demand (ThOD) of 34% in 10 days, and 46% after 20 days. AES is not considered to bioconcentrate in aquatic organisms.

9.1.2. Environment – effects assessment

Ecotoxicity data for AES of varying chain lengths, provided in the Danish EPA report, indicate the notified chemical is expected to have an LC50 for fish of > 24 mg, and an EC50 for algae of >20 mg/L, and an LC50 for *Daphnia magna* of > 1 mg/L. A PNEC, derived using the most sensitive species and a safety factor of 100, is 0.01 mg/L.

9.1.3. Environment – risk characterisation

Location	PEC (μg/L)	PNEC (mg/L)	Risk Quotient (RQ)[(a)]
Australia-wide STPs			
Ocean outfall	3.3 X 10^{-4}	0.01	0.03
Inland River	[b]3.3 X 10^{-3}	0.01	0.33

a. RQ = PEC ÷ PNEC. b. PEC values calculated assuming no attenuation of notified chemical in biosolids and no loss through volatilisation or biodegradation during STP process

On the basis of the RQ values provided in the table above, the low volumes used, and nationwide and diffuse use of the notified chemical, it is not considered to pose an unacceptable risk to the health of aquatic life based on its reported use pattern.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

As the notified chemical will be imported as a component of a bath oil for use by the public, workers are only likely to be exposed in the event of a transport or storage accident. Exposure in these circumstances will be brief and workers would be expected to employed personal protective equipment to prevent skin contact.

9.2.2. Public health – exposure assessment

The shower oil containing the notified chemical is designed to be applied to the hair and body and exposure may be up to 15 g per day which is applied for a short period and washed off.

9.2.3. Human health - effects assessment

On the basis of toxicological data on analogues of the notified chemical, it is expected to be of low acute oral and dermal toxicity, is not likely to be a skin sensitiser and is not likely to be genotoxic. Systemic effects after repeated or prolonged exposure are unlikely as are teratogenic

or carcinogenic effects. However, the notified chemical is likely to be a skin and eye irritant. The notified chemical is most closely related to sodium laureth sulfate and based on the results for this chemical it may be a mild to moderate irritant.

9.2.4. Occupational health and safety – risk characterisation

The risk of skin or eye irritation is considered to be low given that the notified chemical will be imported solely in a consumer product. Clean up of spills from leaking packaging will occur infrequently and impervious gloves and protective clothing should normally be worn during these operations.

9.2.5. Public health – risk characterisation

Normal use of the imported product should not result in irritant effects as it is left on the skin for a short period before being washed off. Some unintended entry into eyes may occur and mild irritation may follow.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R36/38: Irritating to eyes and skin

According to the Globally Harmonised System for the Classification and Labelling of Chemicals (UN, 2003), the notified chemical is categorised as:

	Hazard category	***Hazard statement***
Skin corrosion/ irritation	2 Irritant	Causes skin irritation
Serious eye damage/ eye irritation	2A Irritant	Causes serious eye irritation

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 described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of a product containing the chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is 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 product containing the chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R36/38 Irritating to eyes and skin

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 20%: R36/38 Irritating to eyes and skin

CONTROL MEASURES
Occupational Health and Safety

- 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.

Environment

Disposal

- The notified chemical should be disposed of in landfill.

Spills

- Spills should be contained with absorbent material and placed in a suitable container for disposal.

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

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