File No: STD/1033

25 February 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

ASSESSMENT REPORT
(Exempt Information and Full Public Report)

Poly(oxy-1,2-ethanediyl), α-[2-[bis(2-aminoethyl)methylammonio]ethyl]-ω-hydroxy-, N,N'-bis(C16-18 and C18-unsatd. acyl) derivs., Me sulfates (salts)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

Under subsection 38(5) of the Act the Director of Chemicals Notification and Assessment publishes this assessment report by giving a copy of it to the:

- Chief Executive Officer of the National Occupational Health and Safety Commission;
- Secretary of the Department of Environment and Heritage; and
- Secretary of the Department of Health and Ageing.

This assessment report will not be available for inspection by the public.

Director
NICNAS

EXEMPT INFORMATION

DISTRIBUTION
Concept Chemical Corporation Pty Ltd
NICNAS
Department of Environment and Heritage

Poly(oxy-1,2-ethanediyl), α-[2-[bis(2-aminoethyl)methylammonio]ethyl]-ω-hydroxy-, N,N'-bis(C16-18 and C18-unsatd. acyl) derivs., Me sulfates (salts)

EXEMPT INFORMATION

1. APPLICANT DETAILS

APPLICANT
Concept Chemical Corporation Pty Ltd (ABN 38 001 907 464)
14/33 Ryde Road, Pymble, NSW 2073

3. COMPOSITION

DEGREE OF PURITY
73% of the product Accosoft 780

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	Sulfurous acid, monosodium salt		
CAS No.	7631-90-5	*Weight %*	0.05-0.1% (w/w)
Hazardous Properties	Classification Harmful: R22; R31 Concentration cutoffs Conc≥25%: Xn; R22; R31 (HSIS, 2006).		
Chemical Name	Sulfuric acid, dimethyl ester		
CAS No.	77-78-1	*Weight %*	< 0.00001%
Hazardous Properties	Classification Carcinogenic Category 2: R45 Mutagenic Category 3: R68 Very Toxic: R26 Toxic: R25 Corrosive: R34; R43 Concentration cutoffs Conc≥25%: T+; R45; R26; R25; R34; R43 ≥10%Conc<25%: T+; R45; R26; R34; R22; R43 ≥7%Conc<10%: T+; R45; R26; R22; R36/37/38; R43 ≥5%Conc<7%: T; R45; R23; R22; R36/37/38; R43 ≥3%Conc<5%: T; R45; R23; R22; R43 ≥1%Conc<3%: T; R45; R23; R43 ≥0.1%Conc<1%: T; R45; R20 ≥0.01%Conc<0.1%: T; R45 (HSIS, 2006)		
Chemical Name	Oxirane		
CAS No.	75-21-8	*Weight %*	0

Hazardous Properties Classification
Very Flammable: R12
Carcinogenic Category 2: R45
Mutagenic Category 2: R46
Toxic: R23
Irritant: R36/37/38
Concentration cutoffs
Conc≥5%: T; R45; R46; R23; R36/37/38
≥0.5%Conc<5%: T; R45; R46; R20
≥0.1%Conc<0.5%: T; R45; R46 (HSIS, 2006)

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)

Chemical Name 1,2,3-Propanetriol
CAS No. 56-81-5 *Weight %* Up to 9% (w/w), combined with Poly(oxy-1,2-ethanediyl), α,α', α"-1,2,3-propanetriyltris[ω-hydroxy- of Accosoft 780

Chemical Name Poly(oxy-1,2-ethanediyl), α,α', α"-1,2,3-propanetriyltris[ω-hydroxy-
CAS No. 31694-55-0 *Weight %* Up to 9% (w/w), combined with 1,2,3-Propanetriol of Accosoft 780

ADDITIVES/ADJUVANTS
None

Chemical Name 2-Propanol
CAS No. 67-63-0 *Weight %* 10% (w/w) of Accosoft 780
Hazardous Properties Classification
Flammable: R11
Irritant: R36; R67
Concentration cutoffs
Conc≥20%: ~~Xi;~~ R36 (HSIS, 2006)

5. PROCESS AND RELEASE INFORMATION

IDENTITY OF MANUFACTURER/RECIPIENTS
At present the known site where Accosoft 780 will be reformulated into fabric softener products is:

Hucon Chemicals
5-7 Waldheim Road
Bayswater VIC 3153

6. PHYSICAL AND CHEMICAL PROPERTIES

Flash Point Not determined

Remarks The notified chemical is expected to have negligible volatility, and is therefore not expected to be capable of forming an ignitable mixture with air.

The flash point of the product Accosoft 780 is 31.5°, due to the presence of 10% 2-propanol.

Flammability Limits Not determined

Remarks The notified chemical is not expected to be capable of forming an ignitable mixture with air.

The flammable limits of the product Accosoft 780 are 2-13% in air, on the basis of its 2-propanol content.

Autoignition Temperature Not determined

Remarks The notified chemical is not expected to be capable of forming an ignitable mixture with air.

The autoignition temperature of the product Accosoft 780 is 399°C, based on its 2-propanol content.

7. TOXICOLOGICAL INVESTIGATIONS

Chemical Analogue 2 Data
Data reported below are for the following product that has been accepted as a suitable analogue for the purpose of assessing the toxicological profile of the notified chemical. The product contains 85% partially hydrogenated tallow EQ and 15% 2-propanol.

Chemical Analogue 3 Data
Data reported below are for the following product that has been accepted as a suitable analogue for the purpose of assessing the toxicological profile of the notified chemical. The product contains 90% partially hydrogenated tallow EQ and 10% 2-propanol.

EXEMPT INFORMATION

File No: STD/1033

25 February 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Poly(oxy-1,2-ethanediyl), α-[2-[bis(2-aminoethyl)methylammonio]ethyl]-ω-hydroxy-, N,N'-bis(C16-18 and C18-unsatd. acyl) derivs., Me sulfates (salts)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

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AUSTRALIA

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Director
NICNAS

FULL PUBLIC REPORT

Poly(oxy-1,2-ethanediyl), α-[2-[bis(2-aminoethyl)methylammonio]ethyl]-ω-hydroxy-, N,N'-bis(C16-18 and C18-unsatd. acyl) derivs., Me sulfates (salts)

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Concept Chemical Corporation Pty Ltd (ABN 38 001 907 464)
14/33 Ryde Road, Pymble NSW 2073

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:

Percent weight of hazardous and non-hazardous impurities
Identity of sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

Melting Point/Boiling Point
Density
Vapour pressure
Water Solubility
Hydrolysis as a function of pH
Partition coefficient
Adsorption/Desorption
Dissociation constant
Flash point
Flammability
Autoignition
Explosivity
Reactivity
Acute oral toxicity
Acute dermal toxicity
Skin irritation
Eye irritation
Skin sensitisation
Mutagenicity
In vitro clastogenicity
Biodegradation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Poly(oxy-1,2-ethanediyl), α-[2-[bis(2-aminoethyl)methylammonio]ethyl]-ω-hydroxy-, N,N'-bis(C16-

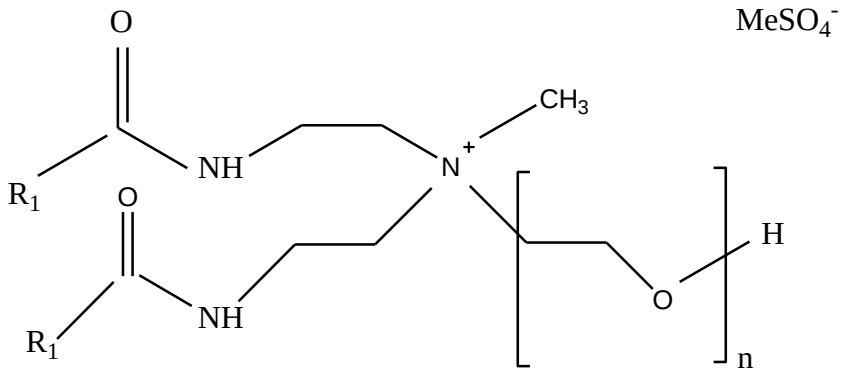
18 and C18-unsatd. acyl) derivs., Me sulfates (salts)

MARKETING NAME
Ingredient in Accosoft 780

CAS NUMBER
468743-76-2

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



Where $R_1C(O)$- = C_{16-18} and C_{18}-unsatd. acyl and n = 1-4 (average2.4-2.7)

MOLECULAR WEIGHT
The notified chemical is a UVCB substance. The average molecular weight of the notified chemical is 866.08.

SPECTRAL DATA

METHOD	Infra Red spectroscopy
Remarks	IR peaks: 3327, 3007, 2926, 2856, 1741, 1652, 1544, 1463, 1378, 1247, 1216, 1127, 1058, 1007, 953, 818 and 763 cm^{-1}
TEST FACILITY	Stepan Company (1999).

METHODS OF DETECTION AND DETERMINATION

METHOD	Potentiometric titration
Remarks	According to the ASTM D5070 "Standard Test Method for Synthetic Quaternary Ammonium Salts in Fabric Softeners by Potentiometric Titrations".
TEST FACILITY	Not reported

3. COMPOSITION

DEGREE OF PURITY
> 70% of the product Accosoft 780

The notified chemical is a UVCB substance that has not been isolated; it is only manufactured in liquid products such as Accosoft 780.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Introduced as an ingredient (> 70%) of the imported product Accosoft 780.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	35	49	56	70	70

USE
Anti-static agent to be used in consumer fabric softener products.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Accosoft 780 will be imported by the notifier and distributed to customers who will reformulate it into fabric softener products.

TRANSPORTATION AND PACKAGING
Accosoft 780 will be imported in steel 200 L drums, and transported by road in commercial carrier trucks either to the notifier's warehouse before distribution to reformulation customers, or directly to the customer's reformulation facilities.

5.2. Operation description

Reformulation
Accosoft 780 will be transferred from product drums to a mixing vessel. Accosoft 780 will be discharged by a single unloading pump. The mixing vessel will typically be 20,000 L maintained under agitation/circulation.

In the mixing vessel, Accosoft 780 will be blended with water and other minor formulants (including colour, thickener, fragrance, preservative, non-ionic surfactants). The blending process can be completed without heating. If heat is used during the blending process, it should not exceed 50°C. The mixing process takes approximately 30-60 minutes.

The product will be transferred by stainless steel dedicated pipeline directly to a filling machine for automated filling into 1.25 L high density polyethylene (HDPE) bottles. The bottles will be packed into cardboard boxes and palletised for transport.

End Use
The packaged fabric softeners will be distributed to retail outlets for sale to the public.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Compounder	1-2	1-2 minutes	48 times/year
Mixing tank operator	1-2	negligible	48 times /year
Quality control chemist	1	1-2 minutes	48 times /year
Filling line operator	1-2	negligible	48 times /year

Exposure Details
Transport & Storage
Waterside workers, transport workers and warehouse workers are only likely to be exposed to the notified chemical in the event of accidental spill involving breach of sealed import drums of Accosoft 780.

Formulation
There is a risk of exposure to the notified chemical for workers involved in transfer of Accosoft 780 into the mixing vessel, and transfer of formulated products into end use containers. Exposure during these operations is expected to be minimal, as the blending/dispensing process will employ a closed, sealed-delivery system. Exposure will be further limited by the use of recommended PPE including goggles, face shield, gloves and protective clothing.

End Use
Workers involved in the end use of the formulated fabric softener products have the greatest potential for exposure to the notified chemical; however, exposure will be limited by the lower concentration of the notified chemical in end use products (5%). Exposure will be further reduced by the use of recommended PPE including goggles, face shield, gloves and protective clothing.

5.4. Release

RELEASE OF CHEMICAL AT SITE

RELEASE OF CHEMICAL FROM USE

5.5. Disposal

5.6. Public exposure
The public will be exposed to the notified chemical via two major routes: contact with textile articles treated with products containing the notified chemical; and direct contact with fabric softener products formulated with Accosoft 780.

Treated Textiles
There is likely to be wide, dispersive exposure to textiles treated with products containing the notified chemical, with direct dermal contact. Exposure will be limited by the low concentration of notified chemical in final textile articles, which is estimated to be 0.005% of fabric weight, and the fact that the majority of this will be fixed to the fibres of the clothing, and not biologically available.

Domestic End Use
There is likely to be wide, dispersive exposure to the notified chemical through end use of domestic fabric softener products. The most likely route of exposure is through dermal contact with fabric softeners. Provided use is in accordance with instructions and warnings provided on product labels, biologically significant exposure is expected to be negligible. In the event of significant exposure, adverse effects are not expected, based on the toxicological profile of the notified chemical (formed principally from data on a chemical analogue).

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	The product Accosoft 780 (> 70% notified chemical) is a clear, yellow liquid. The notified chemical is believed to be a low melting point solid, but is manufactured only in liquid form, in products such as Accosoft 780.

Chemical Analogue Data
Data reported below are for the following chemical, that has been accepted as a suitable analogue for the purpose of assessing physical and chemical properties of the notified chemical:

Chemical Name	Fatty acids C_{10}-C_{20} and C_{16}-C_{18} unsaturated, reaction products with triethanolamine, dimethyl sulphate-quaternised

CAS Number 91995-81-2

Melting Point > 85ºC

Remarks This result is for the analogue chemical, which decomposed slowly at the melting point

Boiling Point > 100ºC at 101.3 kPa

Remarks This result is for the analogue chemical, which decomposed slowly at the boiling point

Density Approximately 1000 kg/m^3

Remarks Based on the density of the analogue chemical

Vapour Pressure Expected to be negligible

METHOD Estimation
Remarks Based on the fact that the notified chemical is an organic salt with a relatively high molecular weight.

Water Solubility < 0.02 g/L at 20ºC

METHOD Hot dispersion in pure water of 90% test substance and 10% solvent, then cooled at 20°C
Remarks This result is for the analogue chemical

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ <hours or days>*
4		
7		
9		

Remarks
TEST FACILITY

Partition Coefficient (n-octanol/water) log Pow = …..at 20ºC

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks HPLC Method/Flask Method
TEST FACILITY

Adsorption/Desorption log K_{oc} = … at …°C
– screening test

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
Remarks
TEST FACILITY

Adsorption/Desorption log K_{oc} = … at …°C
– main test

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.

Soil Type	*Organic Carbon Content (%)*	*pH*	*Koc (mL/g)*

Remarks
TEST FACILITY

Dissociation Constant Not expected to possess any dissociation constants that lie within the environmentally relevant range of pH 4 to 9.

METHOD pKa calculations using ACD/pKa v6.0 model
Remarks The quaternary ammonium group is expected to retain its cationic charge throughout.

Particle Size Not determined

Remarks The notified chemical is believed to be a low melting point solid, but is manufactured only in liquid form (such as the product Accosoft 780), for which particle size is not applicable

Flash Point Not determined

Remarks The notified chemical is expected to have negligible volatility, and is therefore not expected to be capable of forming an ignitable mixture with air.

The flash point of the product Accosoft 780 is 31.5°, due to the presence of flammable solvent.

Flammability Limits Not determined

Remarks The notified chemical is not expected to be capable of forming an ignitable mixture with air.

The flammable limits of the product Accosoft 780 are 2-13% in air, on the basis of its flammable solvent content.

Autoignition Temperature Not determined

Remarks The notified chemical is not expected to be capable of forming an ignitable mixture with air.

The autoignition temperature of the product Accosoft 780 is 399°C, based on its flammable solvent content.

Explosive Properties Not expected to show any explosive tendencies.

METHOD Criteria for assessing explosivity in Bretherick (1990)
Remarks The notified chemical contains none of the functional groups expected to cause or enhance explosivity.

Reactivity Not designed or expected to be reactive in use.

Remarks The main thermal decomposition products of the notified chemical are expected to be carbon monoxide, carbon dioxide and water, together with smaller amounts of oxides of nitrogen and sulfur.

7. TOXICOLOGICAL INVESTIGATIONS

Chemical Analogue 1 Data
Data reported below are for the following chemical that has been accepted as a suitable analogue for the purpose of assessing the toxicological profile of the notified chemical:

Chemical Name Fatty acids C10-C20 and C16-C18 unsaturated, reaction products with triethanolamine, dimethyl sulphate-quaternised
CAS Number 91995-81-2

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 ≥ 5000 mg/kg bw	low toxicity
Rat, acute inhalation	not available
Rabbit, skin irritation (100%)	irritating
Rabbit, skin irritation (20%)	non-irritating
Human volunteers, skin irritation	non-irritating
Rabbit, eye irritation (100%)	irritating
Rabbit, eye irritation (20%)	non-irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence of sensitisation.
Guinea pig, skin sensitisation –non-adjuvant test.	no evidence of sensitisation.
Genotoxicity – in vivo <Bone Marrow Cells of the Mouse>	non genotoxic

Chemical Analogue 2 Data
Data reported below are for the following product that has been accepted as a suitable analogue for the purpose of assessing the toxicological profile of the notified chemical. The product contains partially hydrogenated tallow EQ and solvent.

Endpoint and Result	*Assessment Conclusion*
Rat, acute dermal LD50 > 2000mg/kg bw	low toxicity

Chemical Analogue 3 Data
Data reported below are for the following product that has been accepted as a suitable analogue for the purpose of assessing the toxicological profile of the notified chemical. The product contains partially hydrogenated tallow EQ and solvent.

Endpoint and Result	*Assessment Conclusion*
Rat, repeat dose <gavage> toxicity – 90 days.	NOEL ≥ 300 mg/kg
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo <micronucleus assay>	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Analogue 1

METHOD EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain Rat/Sprague-Dawley
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0
2	5/sex	5000	0

LD50 ≥ 5000 mg/kg bw
Remarks - Results No abnormality in behaviour was noted in the animals treated at the dose level of 2000 mg/kg.
A slight decrease in the spontaneous activity of the animals treated at the dose level of 5000 mg/kg was observed for a few hours after treatment

and was accompanied with a slight slowed down of the body weight gain of the males. From day 2 to day 15, the general behaviour of the females was not influenced by the treatment.
No deaths occurred at the dose levels of 2000 and 5000 mg/kg.
The macroscopic examination revealed no abnormalities in all animals.

CONCLUSION The analogue is of low toxicity via the oral route.

TEST FACILITY Centre International de Toxicologie (1991)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Analogue 2

Species/Strain Rat
LD50 > 2000 mg/kg bw

CONCLUSION The analogue is of low toxicity via the dermal route.

TEST FACILITY Only summary was provided (1991).

7.3. Acute toxicity – inhalation

There was no acute inhalation toxicity test submitted.

7.4.1 Irritation – skin

TEST SUBSTANCE Analogue 1 (100%)

METHOD EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3 male
Observation Period 15 d
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2.7	2.0	0.3	3	d 10	0
Oedema	2.0	2.0	0.3	4	d 2	0

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

Remarks - Results Cutaneous reactions which were slight in one animal and marked in 2 animals were observed after the application of the test substance.
The cutaneous lesions consisted of erythema (scores of 1 to 3) and oedema (scores of 1 to 4) and were no longer observed on day 3 for one animal or between day 8 and day 11 for the other 2 animals. A desquamation of the skin at the treatment site remained between day 8 and day 15.

CONCLUSION The analogue (100%) is irritating to the skin.

TEST FACILITY Centre International de Toxicologie (1991a)

7.4.2 Irritation – skin

TEST SUBSTANCE Analogue 1 (20%)

METHOD
Species/Strain: EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Number of Animals: Rabbit/New Zealand White
Vehicle: 3 male
Observation Period: Water
Type of Dressing: 72 h
Remarks - Method: Semi-occlusive.
No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.7	0	0	1	48 h	0
Oedema	0	0	0	0	-	0

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

Remarks - Results: One hour after the removal of the dressing, no cutaneous reactions were observed in the animals.
After 24 and 48 hours, only a slight erythema was noted in one animal.
No cutaneous reactions persisted after 72 hours.

CONCLUSION: The analogue (20%) is non-irritating to the skin.

TEST FACILITY: Centre International de Toxicologie (1990)

7.4.3 Irritation – skin - human volunteers

TEST SUBSTANCE: Analogue 1

METHOD
Study Group: Open epicutaneous test (Burckhardt-Test)
Observation Period: 20 human volunteers
Remarks - Method: 40 minutes
The analogue was applied in a concentration of 5% AS, 10% AS, 20% AS and 50% AS.
The test solution was continuously applied (1 to 2 drops) with a glass stick to an area of about 3 cm in diameter on the skin of inner surface of the forearm for 30 minutes. The application is repeated each 30 seconds.

RESULTS

Remarks - Results: 20 volunteers applied analogue (5% AS) to the left arm. 1 of 20 volunteers showed a slight erythema after 16 minutes of exposure and which disappeared 10 minutes after the end of application.
The same volunteers applied analogue (10% AS, 20% AS and 50% AS) to the right arm. All volunteers showed no reactions.

CONCLUSION: The analogue is non-irritating to the skin.

TEST FACILITY: Henkel KGaA (1991)

7.5.1 Irritation – eye

TEST SUBSTANCE: Analogue 1 (100%)

METHOD
Species/Strain: EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Number of Animals: Rabbit/New Zealand White
Observation Period: 3 male
8 d

Remarks - Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.7	1.0	2.0	2.0	7 d	0
Conjunctiva: chemosis	2.0	1.3	3.0	3.0	6 d	0
Conjunctiva: discharge	-	-	-	S**	2 d	0
Corneal opacity	0.7	0.3	1.7	2.0	7 d	0
Iridial inflammation	0.0	0.0	1.0	1.0	3 d	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
**S = White purulent discharge

Remarks - Results After the instillation of the test substance, marked conjunctival reactions (chemosis: mean scores at 2.0 or 3.0 in 2 animals and redness: score of 2.0 in one animal, during 72 hours) or moderate (redness in 2 animals and chemosis in one animal) were observed.
After 24, 48 and 72 hours, an irritation of the iris (score 1) was noted in one animal.
Corneal opacity which was slight (score of 1) in 2 animals or moderate (score maximal of 2) for 72 hours in one animal was observed on an area less than a half or less than one quarter of the cornea.
All the ocular lesions had resolved between day 4 and day8.

CONCLUSION The analogue (100%) is irritating to the eye.

TEST FACILITY Centre International de Toxicologie (1991b)

7.5.2 Irritation – eye

TEST SUBSTANCE Analogue 1 (20%)

METHOD EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3 male
Observation Period 3 d
Remarks - Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0.3	0	1	1 d	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	0	-	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results One hour after the instillation of the test substance, slight (chemosis, enanthema) conjunctival reactions were observed in all the animals.
After 24 hours, only a slight redness of the conjunctiva persisted in one animals.
No ocular reactions were noted after 48 and 72 hours.

CONCLUSION The analogue (20%) is non-irritating to the eye.

TEST FACILITY Centre International de Toxicologie (1990a)

7.6.1 Skin sensitisation

TEST SUBSTANCE Analogue 1

METHOD OECD TG 406 Skin Sensitisation - maximisation method.
Species/Strain Guinea pig/Pirbright white
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 0.5%, 1%, 2%, 3% (v/v) with Paraffine perliquid
topical: 5%, 7.5%, 10% (v/v) with Paraffine perliquid
MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
INDUCTION PHASE Induction Concentration:
intradermal: 0.5% (v/v) with Paraffine perliquid
topical: 5% (v/v) with Paraffine perliquid
Signs of Irritation Intradermal injection: An examination of the injections was performed one and 24 hours after treatment. On both dates weak dermal reactions were observed at the test group animals and all but three control group animals had no statement.
Topical induction: At the test group animals one hour after the exposure end weak up to moderate skin reactions were observed and 24 hours later weak skin reactions. The control group animals also showed weak skin reaction on both times.
CHALLENGE PHASE
topical: 2% (v/v) with Paraffine perliquid

Remarks - Method No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after challenge*	
		24 h	*48 h*
Test Group			
	2%	1/20	1/20
Control Group			
	0	0/10	0/10

Remarks - Results 24 and 48 hours after termination of the challenge moderate skin reactions were observed at 19 test group animals and at the 10 control group animals.
Neither test group animals or control group animals died during the study and no significant difference was observed in their body weights.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the analogue under the conditions of the test.

TEST FACILITY Henkel KGaA (1991a)

7.6.2 Skin sensitisation

TEST SUBSTANCE Analogue 1

METHOD OECD TG 406 Skin Sensitisation – Buehler Test.
Species/Strain Guinea pig/Pirbright white
PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 2.5%, 5%, 10%, 15%, 20%, 25%, 30% (w/w) in saline
MAIN STUDY
Number of Animals Test Group: 10 Control Group: 10

INDUCTION PHASE	Induction Concentration: intradermal: 15%
Signs of Irritation	One hour after terminating the third induction, 6 test group animals showed slight and one moderate effects on the exposed skin area. 24 hours later at 9 test group animals shoed up to strong effects. The control group animals showed no dermal alterations on the treated skin areas at any time.
CHALLENGE PHASE	
challenge	topical: 5%
Remarks - Method	No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after challenge*	
		24 h	*48 h*
Test Group			
	5%	0/10	0/10
Control Group			
	0	0/10	0/10

Remarks - Results	24 and 48 hours after termination of the challenge only weak skin alterations were observed at some test group animals and controls. A slight crescendo effect in dermal alterations on at least one exposed animal flank was shown at 40% of the test group animals in contrast with 10% of the controls. Neither test group animals or control group animals died during the study and no significant difference was observed in their body weights.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the analogue under the conditions of the test.
TEST FACILITY	Henkel KGaA (1991b)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Analogue 3
METHOD	OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
Species/Strain	
Route of Administration	Oral – gavage/diet/drinking water.
Exposure Information	Total exposure days: 90 days; Dose regimen: 5/7 days per week; Post-exposure observation period:
Vehicle	
Remarks - Method	No significant protocol deviations.

RESULTS

Mortality and Time to Death

In the course of the study there were no mortality and clinical symptoms of intoxication.

Clinical Observations and Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

In comparison of the control group there was no differences in food intake, body weight gain, haematological parameters, status of the eyes and organ weights which could be considered as attributable to the administration of the test substance.

Effects in Organs

At gross necropsy, effects were observed in the high dose group in the following organs: fore stomach (irritations and even ulcerations) and urinary bladder (epithelium desquamation). These pathological lesions were considered to be treatment related.

Remarks – Results
A further finding in the high dose group consisting of a distinct increase of alanin-aminotransferase in male and female animals indicated possible liver injury.

At the other dose levels there was no treatment related lesions.

CONCLUSION
The No Observed Effect Level (NOEL) was established as ≥ 300 mg/kg bw/day in this study, based on the results.

TEST FACILITY Only summary report was provided (1991).

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Analogue 3

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Species/Strain *S. typhimurium*
Metabolic Activation System
Concentration Range in Main Test a) With metabolic activation: 8, 40, 200, 100 and 5000 µg/plate.
b) Without metabolic activation: 8, 40, 200, 100 and 5000 µg/plate.
Remarks - Results Negative

TEST FACILITY Only summary was provided (1983).

7.10.1 Genotoxicity – in vivo

TEST SUBSTANCE Analogue 1

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain Mice/albino CFW 1 Winkelman
Route of Administration Oral – gavage/diet/drinking water.
Vehicle Water
Remarks - Method No significant protocol deviations.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	6/sex	20 mL	24
II (low dose)	2/sex	3000	
III (mid dose)	2/sex	4000	
IV (high dose)	6/sex	5000	24, 48, 72
V (positive control, CP)	6/sex	10	24

CP=cyclophosphamide

RESULTS
Doses Producing Toxicity
No animals up to the highest dose died within the first three days or showed signs of severe morbidity.
Slight piloerection was observed at all animals up to 24 hours after administration.
Based on the results 5000 mg/kg body weight was selected as appropriate dose for the micronucleus test.
Genotoxic Effects
No increase in the frequency of micronucleated cells was observed.
The incidence of micronuclei in the negative control groups was in the range of historical control data. The positive control substance, cyclophosphamide, induced a statistically significant increase in the number of micronuleated cells in both sexes.
Toxic effects of the test substance as indicated by an increased mortality of test animals were not noticed. A slight reduction in the ratio of polychromatic to normochromatic erythrocytes was determined in female

	mice 24 and 48 hours after administration, indicating possibly a weak toxic effect to the bone marrow.
Remarks - Results	No mortality was registered during the main study. Signs at clinical examination were slight piloerection.
CONCLUSION	The analogue was not clastogenic under the conditions of this in vivo Bone Marrow Cells of the Mouse test.
TEST FACILITY	Henkel KGaA (1990)

7.10.2 Genotoxicity – in vivo

TEST SUBSTANCE	Analogue 3
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mice/albino CFW 1 Winkelman
Route of Administration	Oral – gavage/diet/drinking water.
Exposure Period	24, 48 and 72 hours
Doses	5000 mg/kg bw
Remarks - Results	Negative
CONCLUSION	The analogue was not clastogenic under the conditions of this in vivo test.
TEST FACILITY	Only summary was provided (1983).

8. ENVIRONMENT

8.1. Environmental fate

If no environmental fate data were submitted for a limited notification, write "No environmental fate data were submitted" here. Otherwise, delete this row and fill out the appropriate sections below. For a standard notification, the sections corresponding to all schedule requirements should be filled out, although they may contain justification of variations. Justification of variations or other prose should go in the right hand box below the subsection heading, and all the remainder may then be deleted. For a limited notification, sections corresponding to data not submitted may be deleted and appropriate renumbering done.

8.1.1. Ready biodegradability

TEST SUBSTANCE

METHOD

OECD TG 301 A Ready Biodegradability: DOC Die-Away Test.
OECD TG 301 B Ready Biodegradability: CO2 Evolution Test.
OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
OECD TG 301 E Ready Biodegradability: Modified OECD Screening Test.
OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.

Inoculum
Exposure Period
Auxiliary Solvent
Analytical Monitoring
Remarks - Method

RESULTS

Test substance		*<Reference Substance>*	
Day	*% Degradation*	*Day*	*% Degradation*

Remarks - Results

CONCLUSION

TEST FACILITY

8.1.2. Bioaccumulation

TEST SUBSTANCE

METHOD

OECD TG 305 Bioconcentration: Flow-through Fish Test.
EC Directive 98/73/EC C.13 Bioconcentration: Flow-Through Fish Test.

Species
Exposure Period — Exposure: … days — Depuration: … days
Auxiliary Solvent
Concentration Range — Nominal: … mg/L
Actual: … mg/L
Analytical Monitoring
Remarks - Method

RESULTS

Bioconcentration Factor

CT50
Remarks - Results

CONCLUSION

TEST FACILITY

8.2. Ecotoxicological investigations

If no ecotoxicity data were submitted for a limited notification, write "No ecotoxicity data were submitted" here. Otherwise, delete this row and fill out the appropriate sections below. For a standard notification, the sections corresponding to all schedule requirements should be filled out, although they may contain justification of variations. Justification of variations or other prose should go in the right hand box below the subsection heading, and all the remainder may then be deleted. For a limited notification, sections corresponding to data not submitted may be deleted and appropriate renumbering done.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE

METHOD — OECD TG 203 Fish, Acute Toxicity Test -<insert test type/conditions>.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish -<insert test type/conditions>.

Species
Exposure Period
Auxiliary Solvent
Water Hardness — … mg $CaCO_3$/L
Analytical Monitoring
Remarks – Method

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1h*	*24h*	*48h*	*72h*	*96h*

LC50 — … mg/L at 24 hours.
… mg/L at 48 hours.
… mg/L at 72 hours.
… mg/L at 96 hours.
NOEC (or LOEC) — … mg/L at 96 hours.
Remarks – Results

CONCLUSION

TEST FACILITY

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE

METHOD — OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - <insert test type/conditions>.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - <insert test type/conditions>.

Species	*Daphnia magna*
Exposure Period	… hours *[acute study]* … days *[chronic study]*
Auxiliary Solvent	
Water Hardness	… mg $CaCO_3$/L
Analytical Monitoring	
Remarks - Method	

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h [acute]* *14 d [chronic]*	*48 h [acute]* *21 d [chronic]*

LC50	… mg/L at 24 hours *[acute]* … mg/L at 48 hours *[acute]* … mg/L at …days *[chronic]*
NOEC (or LOEC)	… mg/L at 48 hours *[acute]* … mg/L at …days *[chronic]*
Remarks - Results	

CONCLUSION

TEST FACILITY

8.2.3. Algal growth inhibition test

TEST SUBSTANCE

METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	
Exposure Period	… hours
Concentration Range	Nominal: … mg/L Actual: … mg/L
Auxiliary Solvent	
Water Hardness	… mg $CaCO_3$/L
Analytical Monitoring	
Remarks - Method	

RESULTS

Biomass		*Growth*	
<Elemental Value> mg/L at ... h	*<Elemental Value> ... mg/L*	*<Elemental Value> mg/L at ... h*	*<Elemental value> ... mg/L*

Remarks - Results	

CONCLUSION

TEST FACILITY

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE

METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	
Exposure Period	… hours
Concentration Range	Nominal: … mg/L Actual: … mg/L
Remarks – Method	

RESULTS

IC50	… mg/L
NOEC	… mg/L
Remarks – Results	

CONCLUSION

TEST FACILITY

ADDITIONAL TESTS

8.2E. Inherent biodegradability

TEST SUBSTANCE

METHOD
Inoculum
Exposure Period … hours
Auxiliary Solvent
Analytical Monitoring
Remarks – Method

RESULTS

Test substance		*<Reference Substance>*	
Day	*% Degradation*	*Day*	*% Degradation*

Remarks – Results

CONCLUSION

TEST FACILITY

8.3E. Biochemical/chemical oxygen demand (BOD/COD)

TEST SUBSTANCE

METHOD
Inoculum
Exposure Period
Auxiliary Solvent
Analytical Monitoring
Remarks – Method

RESULTS

BOD (5 days) g/g	*COD g/g*	*BOD/COD*

Remarks – Results

CONCLUSION

TEST FACILITY

8.4E. Photodegradation

TEST SUBSTANCE

METHOD
Light source and Spectrum
Relative Intensity
Spectrum of Test Substance
Exposure Period
Remarks – Method

RESULTS
Remarks - Results

CONCLUSION

TEST FACILITY

BLANK TEMPLATE BOX

8.5E. Endpoint

TEST SUBSTANCE

METHOD
Remarks - Method

RESULTS
Remarks - Results

CONCLUSION

TEST FACILITY

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

9.1.2. Environment – effects assessment

9.1.3. Environment – risk characterisation

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Formulation

Dermal and possibly ocular exposure to the notified chemical could occur during the transfer of the fragrance mixture to the blending vessel. The level of exposure would vary from site to site depending on the level of automation of the formulation process. The estimated dermal exposure is 294 mg/day, based on EASE model using reasonable worst case defaults for the exposure scenario 'manual addition of liquids' (European Commission, 2003) and assuming the notified chemical is present at concentration of 70%. Therefore, for a 70 kg worker and a 100% dermal absorption factor, systemic exposure is estimated to be 4.2 mg/kg bw/day.

Exposure would be further limited by the use of PPE.

Following formulation of the end use products, exposure to the notified chemical is expected to be very low due to the low concentration of the notified chemical (5%) and the expected use of PPE.

End use

Workers may be exposed to the notified chemical during final application of the formulated cleaning/cosmetic products or during their addition to water if dilution is required. Although the level and route of exposure will vary depending on the method of application and work practices employed, exposure is considered to be low due to the low concentration of the notified chemical (5%).

9.2.2. Public health – exposure assessment

Since the notified chemical will be in products sold to the general public, widespread public exposure to the notified chemical at a concentration up to 5% is expected. Based on exposure to a range of household, personal care and cosmetic products in Europe (SDA, 2005), public exposure (dermal and inhalation) to the notified chemical through use of a wide range of products containing the notified chemical, is estimated to be 7.9 mg/kg bw/day, assuming a bodyweight of 60kg, a 100% dermal absorption factor, a concentration of 3% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. This estimate is considered to be an overestimate as it assumes all products (household, personal care and cosmetic) used by one person contain the notified chemical and uses the maximum 'product amount used' from the range in the dataset.

Based on exposure to a range of household, personal care and cosmetic products in Europe (SDA, 2005), maximum single product use exposure is expected for the products: fragrance cream, facial moisturiser, body lotions and hand moisturiser. Exposure to the notified chemical in these products assuming a bodyweight of 60kg, a 100% dermal absorption factor, a concentration of 3% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe, is as follows:

Fragrance cream: 0.7 mg/kg bw/day
Facial moisturiser: 0.8 mg/kg bw/day

Body lotion: 2.8 mg/kg bw/day
Hand moisturiser: 2.8 mg/kg bw/day

If the notified chemical is used in baby care products, a child's exposure is estimated to be 9.7 mg/kg bw/day assuming a bodyweight of 15kg, a 100% dermal absorption factor, a concentration of 3% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. Since products containing the notified chemical are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

9.2.3. Human health – effects assessment

Toxicokinetics, metabolism and distribution.
Acute toxicity.
Irritation and Sensitisation.
Repeated Dose Toxicity (sub acute, sub chronic, chronic).
Mutagenicity.
Carcinogenicity.
Toxicity for reproduction.
Observations on Human Exposure.
Hazard classification for health effects.

Based on the available data, the notified chemical is classified/not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002).

9.2.4. Occupational health and safety – risk characterisation

Reasonable worst-case exposure to the notified chemical during formulation was estimated to be 3 mg/kg bw/day. Based on a NOAEL of 1000 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 330. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for formulation workers.

Following formulation of the end use products, exposure is expected to be very low and as such the risk to workers is also considered to be low.

9.2.5. Public health – risk characterisation

Based on a NOAEL of 1000 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) from a number of exposure scenarios is calculated as follows:

Product(s) used	*Adult/Child*	*Estimated Exposure <mg/kg bw/day>*	*MOE*
Wide range of household, personal care and cosmetic products.	Adult	7.9	130
Fragrance cream	Adult	0.7	1400
Facial moisturiser	Adult	0.8	1300
Body lotion	Adult	2.8	360
Hand moisturiser	Adult	2.8	360
Baby care products	Child	9.7	100

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. As the all the calculated MOEs are > 100, the risk to public health is considered to be low.

Since products formulated with the notified chemical will be stored and used in a domestic environment, there is also the possibility for children to be exposed to the notified chemical by accidental ingestion. However, as the notified chemical is considered to be of low acute toxicity

and given the low concentration of the notified chemical in the formulated products, the risk of lethal effects as a result of accidental ingestion is considered to be low.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

According to the United Nations (2003) Globally Harmonised System for the Classification and Labelling of Chemicals, a **Chronic II** classification is considered appropriate for the notified chemical.

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.
or
The chemical may pose a risk to the environment based on the notified use pattern. Further work or actions (such as additional testing in the area of concern, detailed exposure analysis, in-depth risk assessment or further risk management actions) should be considered.

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 in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical (and products containing the notified chemical) provided by the notifier was (were) in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is (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 products containing the notified chemical) provided by the notifier was (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

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following [health, environmental and physico-chemical] hazard classification for the notified chemical:
  - *[List risk and safety phrases]*

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - [concentration cut-off]: risk phrases *[List]*

- The National Drugs and Poisons Standing Committee (NDPSC) should consider the notified chemical for listing on the SUSDP.
  - *[List safety directions and first aid instructions if required]*

- Products containing more than [X%] notified chemical and available to the public must carry the following safety directions on the label:
  - *[Safety directions and first aid instructions]*

- The notified chemical should be classified as follows under the ADG Code:
  - *[Class and packing group etc]*

- Suppliers should label the notified chemical as a Class [X] dangerous good with the signal word [Labelling COP signal word] and the risk and safety phrases listed above.

Exposure Standard

- The NOHSC Chemicals Standards Sub-committee should consider establishing a national exposure standard for the notified chemical. Based on [health effects and exposure data and/or overseas occupational exposure standards and limits], an atmospheric concentration of [X ppm] is suggested, with this report serving as supporting documentation.

Health Surveillance

- The notified chemical should be considered by NOHSC for development of health surveillance guidelines.

- As the notified chemical is a [health hazard], employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of [the health effect].

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following [isolation and] engineering controls to minimise occupational exposure to the notified chemical [as introduced, as diluted for use, in the product xxx]:
  - *[List control measures]*

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical [as introduced, as diluted for use, in the product xxx]:
  - *[List control measures, Codes of Practice etc]*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical [as introduced, as diluted for use, in the product xxx]:
  - *[List PPE]*

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

- Atmospheric monitoring should be conducted [by ……] to measure workplace concentrations during (manufacture, formulation, use) of the notified chemical.

- 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 ……] to minimise public exposure to the notified chemical:
  - *[List]*

Environment

- The following concentration limits should be implemented [by ……] for release of the notified chemical to the environment:
  - *[List limits]*

- The following control measures should be implemented by [by ……] to minimise environmental exposure during (manufacture, formulation, use) of the notified chemical:
  - *[List control measures]*

- The following monitoring should be conducted [by ……] to measure environmental release during (manufacture, formulation, use) of the notified chemical:
  - *[List methods of monitoring]*

Disposal

- The notified chemical should be disposed of by [method of disposal].

Storage

- The following precautions should be taken [by ……] regarding storage of the notified chemical:
  - *[List]*

Emergency procedures

- Spills/release of the notified chemical should be handled by [method of treatment].

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.

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