File No: STD/1012

28 August 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

EUCAROL AGE/SS

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

EUCAROL AGE/SS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
International Chemicals Pty Ltd (ABN 74 057 313 630)
20 Harper Street Abbotsford VIC 3067

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
The following details are claimed exempt from publication:
Chemical name
Other name
CAS number
Molecular formula
Structural formula
Molecular weight
Spectral data
Chemical constituents
Exact import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements are claimed for some of the physico-chemical properties and some toxicological studies.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Not applicable

NOTIFICATION IN OTHER COUNTRIES
EU (registered as No Longer Polymer); USA (registered in TSCA); Canada (CEPE review in progress).

2. IDENTITY OF CHEMICAL

MARKETING NAME
EUCAROL AGE/SS (a product of Cesalpinia Chemicals S.p.a)

SPECTRAL DATA IR Spectra

TEST FACILITY Cesalpinia Chemicals S.p.A

3. COMPOSITION

DEGREE OF PURITY Not determined

HAZARDOUS IMPURITIES No residual starting material is present in the final formulation

ADDITIVES/ADJUVANTS
None

DEGRADATION PRODUCTS
No degradation products are present in the formulation

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as EUCAROL AGE/SS, a 45% aqueous solution of the notified chemical. It will be used in the manufacture of shampoos, baby shampoos, feminine douches, foam baths and shower gels, at a final concentration of about 2% in shampoos to a maximum of about 10% in bath foam.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<15	<15	<15	<15	<15

USE
The notified polymer will be used as a component of shampoos, baby shampoos, feminine douches, foam baths and shower gels.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not specified

IDENTITY OF MANUFACTURER/RECIPIENTS
Not specified

TRANSPORTATION AND PACKAGING
EUCAROL AGE/SS is imported in drums in liquid form. The products containing the notified chemical will be repackaged in HDPE plastic containers at various sizes (100-300 mL).

5.2. Operation Description

EUCAROL AGE/SS is mixed with different components for final formulation in process vessels that are fully enclosed. Splash proof sanitary pumps transfer the product to modern high speed filling machines.

5.4. Release

RELEASE OF CHEMICAL AT SITE
During formulation of the hair care and personal hygiene products, it is estimated that up to 1% per annum of notified chemical will be released into the environment as a result of spills and equipment cleaning. This equates up to 500 kg per annum.

Presumably machinery and pumping equipment will be cleaned with water and waste from this process will be used in subsequent formulations. It is expected that the import drums containing residual solution will be washed with water and the drums either recycled or disposed of in landfill. The drum washings are expected to be used in subsequent formulations. The consumer containers in which the formulated product will be sold to consumers and the residues they contain will be disposed of in domestic landfill.

RELEASE OF CHEMICAL FROM USE
The majority of the notified chemical will be incorporated into hair care and personal hygiene products and as such will almost completely be released to the environment.

5.5. Disposal

The notified chemical will ultimately be disposed of in either the sewer (major) or landfill.

6. PHYSICAL AND CHEMICAL PROPERTIES

Eucarol AGE-SS is a 45% aqueous solution of the notified chemical. A number of the physical and chemical properties were performed on the aqueous solution.

Appearance at 20ºC and 101.3 kPa Yellow/brown liquid (aqueous solution)

Boiling Point 98 ºC at 101.3 kPa

Remarks Boiling range of the aqueous solution was determined using a distillation method (OECD TG 103). Degradation of the test substance began at approximately 103ºC, with caramelization completed at approximately 160ºC.

TEST FACILITY Biolab Spa-sede Vimodrone (2001)

Density 1140 kg/m^3

Remarks Measured on aqueous solution

TEST FACILITY Cesalpinia Chemicals SpA (2001)

Vapour Pressure 0.34 kPa at 20ºC

Remarks The notifier indicates that the vapour pressure was determined in accordance with OECD TG 104 using a static measurement procedure. The report provided is in Italian so no further assessment of the report could be undertaken. However, the vapour pressure was measured for the aqueous solution and the value reflects the water content.

TEST FACILITY Biolab Spa-sede Vimodrone (2001)

Water Solubility 686 mg/g at 25ºC

Remarks The water solubility of the notified chemical was determined by visual assessment using methodology based on Karl Fischer determination on an aqueous product sample subjected to progressive evaporation until solid appears.

TEST FACILITY Cesalpinia Chemicals SpA Laboratory (2001)

Hydrolysis as a Function of pH Not determined

Remarks The notified chemical contains an ester and glycoside linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur. The notifier has estimated that the notified chemical will have a DT50 of greater than 200 days in the pH range 6-8 and less than 200 days at or below pH 5 and at or above pH 9.

Partition Coefficient (n-octanol/water) log Pow at 20ºC <-2.8

METHOD OECD TG 107 Partition Coefficient (n-octanol/water), Shake Flask Method.

Remarks The partition coefficient of log Pow < -2.8 indicates that the notified chemical is hydrophilic and is likely to partition mainly into the aqueous phase.

TEST FACILITY Biolab Spa-sede Vimodrone (2001)

Adsorption/Desorption Not determined

Remarks The notified chemical is water soluble and as a consequence is expected to be mobile in both aquatic and terrestrial compartments. However, it may chelate by virtue of its anionic character.

Using a structure estimation method based on molecular connectivity indexes, the Koc for bis(2-ethylhexyl)sodium sulfosuccinate can be estimated to be about 1041.

Dissociation Constant Not determined

Remarks The notified chemical contains fully dissociated carboxylate and sulphonate groups. However, the former will become the free acid at pH <5.

Particle Size Not applicable
Remarks Notified chemical is a liquid solution

Flash Point Not determined
Remarks Notified chemical is an anionic surfactant produced directly in water

Flammability Limits Not flammable
Remarks Notified chemical is an anionic surfactant produced directly in water

Autoignition Temperature Not expected to ignite
Remarks Notified chemical is an anionic surfactant produced directly in water

Explosive Properties Not explosive
Remarks Notified chemical is an anionic surfactant produced directly in water

Reactivity
Remarks Notifier indicates that the notified chemical is stable under work and storage conditions up to 100ºC. The boiling point test on the aqueous solution indicated degradation of the notified chemical beyond 103ºC.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >5 000 mg/kg bw	Low toxicity
Rat, acute dermal	No toxicity data were submitted
Rat, acute inhalation	No toxicity data were submitted
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Slightly to moderately irritating
Guinea pig, skin sensitisation - adjuvant test.	No evidence of sensitisation.
Rat, repeat dose toxicity	No toxicity data were submitted
Genotoxicity - bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro	No toxicity data were submitted
Genotoxicity – in vivo	No toxicity data were submitted
Rat, vaginal irritation	Slightly irritating
Irritation, HET-CAM test	Lower irritation scores than SDS.

7.1. Acute toxicity – oral

TEST SUBSTANCE EUCAROL APG/SS

METHOD Similar to EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain Rat/Wistar
Vehicle Water
Remarks - Method No GLP or QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5 000	0/10

LD50 > 5 000 mg/kg bw
Signs of Toxicity Four males and two females had a slight piloerection.
Effects in Organs Two males had a slight mucosa enteritis.
Remarks - Results None

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY Biolab SGS (1993a).

7.2. Acute toxicity - dermal

No toxicity data were submitted.

7.3. Acute toxicity - inhalation

No toxicity data were submitted.

7.4. Irritation – skin

TEST SUBSTANCE EUCAROL APG/SS

METHOD Similar to EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Vehicle None.
Observation Period 7 days.
Type of Dressing Occlusive
Remarks - Method No GLP or QA.

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	0	0	1	1 hour	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 Primary irritating index (PII) = 0.25

CONCLUSION The notified chemical is slightly irritating to skin.

TEST FACILITY Biolab SGS (1993b).

7.5. Irritation - eye

TEST SUBSTANCE EUCAROL APG/SS

METHOD Similar to EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 7 days
Remarks - Method No GLP or QA.
Discharge of conjunctiva was not observed.

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	1.3	1.7	1.3	3	72 hours	0
Conjunctiva: chemosis	0.7	0.7	1.0	2	48 hours	0
Conjunctiva: discharge				Not observed in the study.		
Corneal opacity	0	0.3	0	1	24 hours	0
Iridial inflammation	0.3	0.7	0.3	1	48 hours	0

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

Remarks - Results: The mean scores for redness, chemosis, corneal opacity and iridial inflammation at 1 hour were 3, 2, 1 and 1, respectively. Slight to moderate eye irritation was observed; it is not classifiable as an irritant according to the NOHSC Approved Criteria (NOHSC, 1999).

CONCLUSION: The notified chemical is slightly to moderately irritating to the eye.

TEST FACILITY: Biolab SGS (1993c).

7.6. Skin sensitisation

TEST SUBSTANCE: EUCAROL APG/SS

METHOD: Similar to OECD TG 406 Skin Sensitisation – maximisation method.
Species/Strain: Guinea pig/Albino Hartley
PRELIMINARY STUDY: Maximum Non-irritating Concentration: not provided.

MAIN STUDY
Number of Animals: Test Group: 10 Control Group: 5
induction phase: Induction Concentration:
intradermal injection 100%
topical application 100%
Signs of Irritation: Not stated.
CHALLENGE PHASE
1st challenge: topical application: 100%
Remarks - Method: No GLP or QA.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		48 h	*72 h*	*24 h*	*48 h*
Test Group	100%	0/10	0/10		
Control Group	100%	0/5	0/5		

Remarks - Results: No positive controls were included in the study.

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

TEST FACILITY: Biolab SGS (1995).

7.7. Repeat dose toxicity

No toxicity data were submitted.

7.8. Genotoxicity - bacteria

TEST SUBSTANCE	EUCAROL APG/SS
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure & Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	S9 mix
Concentration Range in Main Test	Test 1: a) With metabolic activation: 0-5 000 µg/plate (plate incorporation). b) Without metabolic activation: 0-5 000 µg/plate (plate incorporation). Test 2: a) With metabolic activation: 0-1 500 µg/plate (pre-incubation). b) Without metabolic activation: 0-1 500 µg/plate (plate incorporation).
Vehicle	Water
Remarks - Method	GLP & QA

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1		≥1 500	Not observed.	Not observed.
Test 2		≥1 500	Not observed.	Not observed.
Absent				
Test 1		≥1 500	Not observed.	Not observed.
Test 2		≥1 500	Not observed.	Not observed.

Remarks - Results	The positive controls had appropriate responses in the study.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Istituto di Ricerche Biomediche (1996).

7.9. Genotoxicity – in vitro

No toxicity data were submitted.

7.10. Genotoxicity – in vivo

No toxicity data were submitted.

7.11. Irritation – vaginal

TEST SUBSTANCE	EUCAROL APG SS
METHOD	In house protocol.
Species/Strain	Rat/Wistar
Number of Animals	10 for the test group and 10 for the control group.
Vehicle	None.
Observation Period	
Treatment	0.2 mL test substance was instilled into vagina by a cathetere. This procedure was repeated 3 times/day for 4 days. All animals were sacrificed 24 hours after treatment.
Remarks - Method	The control group had physiological solution. A modified Draize scale system was used for evaluation.

RESULTS

	Test Animals		*Control Animals*	
Lesion	*Mean Score**	*Maximum Value*	*Mean Score*	*Maximum Value*
Erythema/Eschar	1.7	2	0	0
Oedema	0	0	0	0
Exudate	0	0	0	0

*Calculated on the basis of the scores at necropsy for ALL animals.

Remarks - Results: Well-defined erythema was seen in 7 test animals and very slight erythema was seen in 3 test animals.

CONCLUSION: The notified chemical is slightly irritating to vaginal mucosae.

TEST FACILITY: Biolab s.r.l. (1995).

7.12. Irritation – Hen's Egg Test (HET) -Chorionallantoic Membrane (CAM)

TEST SUBSTANCE: EUCAROL AGE/SS, EUCAROL AGE/EC and EUCAROL AGE/ET.

METHOD: Following the INVITTOX protocol Number 47 (INVITTOX, 1992).
- Species: White Leghorn chicken egg
- Number of Eggs: 3 eggs for each test solution.
- Observation Period: 5 minutes.
- Treatment: After a 10-day incubation at 37.5°C, shell over the air section of each egg was pared off and the egg membrane was removed. A 0.3 mL test solution was added on the CAM and effects of haemorrhage, vascular lysis and coagulation were observed over a period of 5 minutes.
- Remarks - Method: The method is undergoing validation to replace Draize rabbit eye test in Germany. The irritation score is calculated based on the degree of haemorrhage, vascular lysis and coagulation.

RESULTS

Test solution	***Irritation Score***
controls	
NaOH (0.9%)	16.5
Sodium dodecyl sulphate (1%)	12.0
Samples	
Sodium dodecyl sulphate (1)	16.5
Sodium dodecyl sulphate (2)	18.0
Alkyl polyglucoside (APG)	15.0
EUCAROL AGE/SS	12.1
EUCAROL AGE/EC	10.0
EUCAROL AGE/ET	8.9

Remarks - Results: Individual scores of each test solution were not provided in the report.

The irritation scores for the controls are expected to be about 15 for NaOH (0.9%) and 10 for SDS (1%).

CONCLUSION: Three EUCAROL AGE products had lower irritation scores than the other tested surfactants (SDS and APG).

TEST FACILITY: Cesalpinia Chemicals (no date supplied).

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	EUCAROL AGE/SS
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Freeze dried bacteria
Exposure Period	28 Days
Analytical Monitoring	CO_2 release
Remarks - Method	The notifier has provided an English translation of the summary of an Italian test report. Biodegradation was determined by the measurement of biological oxygen demand after the medium was inoculated and stored in the dark for 28 days. Phthalic acid, disodium salt was used as the standard material.

RESULTS

EUCAROL AGE/SS		*Phthalic acid, disodium salt*	
Day	*% degradation*	*Day*	*% degradation*
14	52.2	14	64.2
28	66.3	28	73.0

Remarks - Results	The biodegration of the reference substance was 73% after 28 days, indicating the test conditions were valid. After 28 days, biodegradation of the test substance was 66.3%.
CONCLUSION	The notified chemical is not considered to be readily biodegradable under the conditions of OECD TG 301D, as it failed the criteria of greater than 60% degradation within 10 days of it reaching 10% degradation.
TEST FACILITY	Lamberti Spa (1997).

8.1.2 Inherent biodegradability

TEST SUBSTANCE	EUCAROL AGE/SS
METHOD	The notifier has provided an English translation of the summary of an Italian test report.
Inoculum	From waste water treatment plant of Lamberti SpA.
Exposure Period	14 days
Analytical Monitoring	COD decrease

RESULTS

EUCAROL AGE/SS		*Diethylene glycol*	
Day	*% degradation*	*Day*	*% degradation*
7	69.8	7	11.8
14	80.5	14	94.5

Remarks - Results	The biodegradation of the reference substance, diethylene glycol was 94.5% after 14 days, indicating the test conditions were valid. After 14 days, 80.5% of the test substance had biodegraded.
CONCLUSION	The notified chemical can be considered to be inherently biodegradable.
TEST FACILITY	Lamberti Spa (1995).

8.1.3. Bioaccumulation

Data regarding the bioaccumulation potential of the notified chemical

were not provided for this notification. The notified chemical's low partition coefficient and high water solubility suggests that there is no potential for bioaccumulation (Connell 1990).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE — EUCAROL AGE/SS (45% aqueous solution)

METHOD — OECD TG 203 Fish, Acute Toxicity Test-continuous flow through

Species	Rainbow trout (*Oncorhynchus mykiss*)
Water Hardness	170 mg $CaCO_3$/L
pH Range	7.9-8.05
Temperature	14°C
Exposure Period	96 h
Analytical Monitoring	Liquid chromatography-mass spectrometry

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	ND	20	0	0	0	0	0
4.27	4.22	20	0	0	0	0	0
9.39	9.62	20	0	0	0	0	0
20.7	23.4	20	0	0	18	20	20
44.5	40.9	20	0	20	20	20	20
100	100	20	20	20	20	20	20

LC50	6.75 mg/L at 96 hours (95% confidence level of 4.3-10.5 mg/L). (for the notified chemical)
NOEC	1.2 mg/L at 96 hours.
Remarks – Results	The results of the definitive study showed that no mortalities were observed in the test vessels with less than 9.62 mg/L of test substance. At all test substance concentrations and in the control, fish exhibited sub-lethal effects such as discolouration, hyperventilation, lethargy and loss of coordination. After 96 h, 100% mortality was observed at a measured test concentration of 23.4 mg/L of the test substance. The 96-hour EC_{50} for the notified chemical to *Oncorhynchus mykiss* is 6.75 mg/L as determined by non-linear interpolation.

CONCLUSION — The notified chemical is moderately toxic to fish.

TEST FACILITY — Huntington Life Sciences (2000a)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE — EUCAROL AGE/SS (45% aqueous solution)

METHOD — OECD TG 202 Daphnia sp. Acute Immobilisation Test-Flow through conditions

Species	*Daphnia magna*
Exposure Period	48 hours
Water Hardness	158 mg $CaCO_3$/L
pH Range	7.98-8.14
Temperature	20°C

Analytical Monitoring	Liquid chromatography-mass spectrometry

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	20	0	0
7.5	8.22	20	0	0
15	17.8	20	0	0
30	35.2	20	0	0
60	60.1	20	9	20
120	124	20	19	20

LC50	20.7 mg/L at 48 hours (95% confidence level of 15.2-27.1 mg/L). (for the notified chemical)
NOEC (or LOEC)	15.8 mg/L at 48 hours
Remarks - Results	The immobilisation tests with *Daphnia* were performed in duplicate using 10 daphnids per flask with observations performed at 24 and 48 hours. After 48 h, no immobilised daphnids were observed in the test vessels with less than 35.2 mg/L test substance, while 100% immobilisation was observed at test concentrations above 60.1 mg/L. The 48-hour EC_{50} for the notified chemical to *Daphnia magna* is 20.7 mg/L as determined by non-linear interpolation.
CONCLUSION	The notified chemical is slightly toxic to daphnia.
TEST FACILITY	Huntington Life Sciences (2000b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	EUCAROL AGE/SS (45% aqueous solution)
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
pH range	7.3-7.6
Temperature	21.2-22.5°C
Mean Starting Cell Density	1×10^4 per mL
Concentration Range Nominal	3.13, 6.25, 12.5, 25, 50 and 100 mg/L
Concentration Range Actual	3.14, 6.54, 14.0, 23.6, 53.9 and 94.3 mg/L
Analytical Monitoring	Liquid chromatography-mass spectrometry

RESULTS

Biomass	*Growth*	*NOEC*
E_bC50 mg/L at 72 h	*E_rC50 mg/L at 72 h*	*mg/L at 72 h*
4.2 (CI = 3.8-4.6)	7.6 (CI = 6.9-8.3)	2.9

Remarks - Results	Algae were exposed to the test substance at the measured concentrations of 3.14, 6.54, 14.0, 23.6, 53.9 and 94.3 mg/L for 72 h at 24˚C under constant illumination and shaking. No abnormalities were detected in any of the replicate test samples. Both biomass and growth rate of *Scenedesmus subspicatus* were adversely affected by the test substance. Furthermore, the notifier indicates that after the completion of the test an aliquot (1 mL) of the test solution was taken from the concentrations of

test substance that had exhibited significant inhibition and were added to fresh medium. This solution was incubated under the environmental conditions employed in the definitive test for a period of nine days. The results showed the rate at which growth was re-established in the cultures ranged from three to seven days indicating the notified chemical is algistatic.

CONCLUSION The notified chemical is moderately toxic to algae and is algistatic.

TEST FACILITY Huntington Life Sciences (2000c)

8.2.1. Acute toxicity to *Artemia salina*

TEST SUBSTANCE EUCAROL AGE/SS (45% aqueous solution)

METHOD 24 h Acute Toxicity Test- The notifier has provided an English translation of a summary of an Italian test report.

Species	*Artemia salina*
Exposure Period	24 h
Analytical Monitoring	Not specified

RESULTS

Concentration mg/L Nominal	*Number of Organisms*	*% Mortality 24 h*
5	20	10
10	20	25
15	20	70

LC50	6.5 mg/L at 24 hours (notified chemical)
Remarks – Results	The 24-hour EC50 for the notified chemical to *Artemia salina* was determined by non-linear interpolation.

CONCLUSION The ecotoxicity data indicates the notified chemical is moderately toxic to *Artemia salina*.

TEST FACILITY Lamberti Spa (1998).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The intended use pattern of the notified chemical is expected to result in the majority of the chemical being eventually released to the aquatic environment. However, this will be in dilute manner as the notified chemical contained within the hair care products will be released from domestic use at low concentrations. Here, the notified chemical is expected to eventually partition to soil/sediment and slowly degrade through biological and abiotic processes to water and oxides of carbon and sulphur.

In a worst case situation, based on maximum annual imports of 50 tonnes per annum, all of which is released to sewer and assuming that none is removed during sewage treatment processes, assuming a national population of 19,500,000 and that each person contributes an average 150 L/day to overall sewage flows, the Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as 47 μg/L.

Amount of EUCAROL AGE/SS entering sewer annually 50000 kg
Population of Australia
19.5 million

Amount of water used per person per day	150 L
Number of days in a year	
365	
Estimated PEC	47

μg/L (47 ppb)

When released to receiving waters, the concentration is generally understood to be reduced by a further factor of at least 10, and so the PEC is around 0.47 μg/L.

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate the notified chemical is moderately toxic to fish, algae and *Artemia salina* and slightly toxic to daphnia. The most sensitive species are algae, where the 72-hour E_bC50 is 4.2 mg/L and the NOEC was 2.9 mg/L.

A predicted no effects concentration (PNEC) can be determined when at least one acute EC50 for each of the three trophic levels is available (ie. fish, *Daphnia*, algae). The PNEC is calculated by taking the EC50 value of the most sensitive species, and dividing this value by an assessment safety factor of either 100 (OECD) or 1000 (EU). Using a worst case scenario safety factor of 100, the PNEC is 42 μg/L.

9.1.3. Environment – risk characterisation

The notified chemical will be used as a surfactant in shampoos, baby shampoos, feminine douches, foam baths and shower gels, and most will eventually be released into domestic sewage systems as a consequence of product use. The compound is not readily biodegradable (66% over 28 days but fails the 10 day window criteria) but can be considered to be inherently biodegradable. It has a low partition coefficient of log Pow -2.8, and a high water solubility (686 g/L), indicating that the notified chemical will be mobile in both aquatic and terrestrial compartments. However, as a consequence of its anionic character and expected chelating ability, it will eventually partition to sediment where it is expected to degrade to water and oxides of carbon and sulphur through biological processes.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is 0.011. This value is significantly less than 1, indicating no immediate concern to the aquatic compartment.

The above considerations indicate minimal hazard to the environment when the notified chemical is used as a component of domestic products in the manner and levels indicated by the notifier.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Categories of workers likely to be exposed to the notified chemical are those involved in transport, storage and delivery, and formulation of the products containing notified chemical. The notifier estimated up to 200 workers may handle the notified chemical/products. Two workers are involved in sampling and four workers in testing the batch. During manufacturing and dispensing, 12 workers and up to 10 packing workers are estimated.

Dermal and inhalation exposure may occur when opening the drums containing notified chemical, transferring into mixing vessels, and during sampling and testing and cleaning up spills and equipment. Accidental ocular exposure may also occur. The worst case scenario is considered to be when workers are handling the imported notified chemical (45% aqueous solution). The notifier indicated that during reformulation of the products, the process vessels are fully enclosed and transfer lines using pumps are connected directly from the drums to the mixing vessel. Exposure during these activities is expected to be limited.

During transport and packaging, exposure is only likely in the event of spills or packaging breach.

9.2.2. Public health – exposure assessment

It is expected that during transport, storage and industrial use, exposure of the general public to

the notified chemical will be low.

Public exposure to the notified chemical will occur from the use of personal care products containing the notified chemical. Exposure will be primarily via dermal contact, with minimal inhalation exposure and the possibility of accidental ocular exposure.

9.2.3. Human health - effects assessment

Limited toxicological data were available for the notified chemical.

The notified chemical was of low acute oral toxicity in rat. It was a slight skin irritant in rabbits and was not a skin sensitiser in guinea pigs. Upon application of the notified chemical into rabbit eyes, slight to moderate eye irritation was observed.

The notifier provided two additional studies for the notified chemical. EUCAROL APG/SS was a slight irritant when applied into rat vagina. In the hen's egg test (HET) with chorionallantoic membrane (CAM), the three EUCAROL products including EUCAROL AGE/SS showed lower irritation scores than SDS and APG, which indicated that the eye irritancy effect of the notified chemical could be low.

The notified chemical was not mutagenic in the Ames test with and without S9-mix.

Based on the toxicological data available, the notified chemical would not be classified as a hazardous substance in accordance with the NOHSC Approved Criteria (NOHSC, 1999). However, it is noted that the studies were performed on the 45% aqueous solution of the notified chemical. The notifier has chosen to classify the product as an eye irritant with the risk phrase R36-Irritating to eyes.

9.2.4. Occupational health and safety – risk characterisation

Based on the oral LD50 of >5000 mg/kg bw, and assuming a dermal default absorption factor of 10%, a 70 kg worker exposed dermally to 3500g notified chemical, or 5833 L EUCAROL AGE/SS may reach the lethal dose. These calculations do not include a safety factor. However, workers are not expected to be exposed to such large amounts.

The notified chemical is a slight skin irritant and slight to moderate eye irritant. There is a risk of dermal exposure and accidental ocular exposure when transferring the notified chemical into mixing vessels, testing, repacking and when cleaning up spills and equipment. Formulation workers handling EUCAROL AGE/SS should wear protective gloves and safety glasses or goggles. The risk of inhalation exposure is low as the notified chemical is imported in water solution, is of low volatility and aerosol formation is minimised by use of enclosed mixing vessels. Also, local exhaust ventilation will be used during formulation.

The risk of irritant effects in workers handling the finished personal care products is low as the notified chemical has been further diluted to a maximum of 10% in the product and the process is largely enclosed. The health risk to transport and storage workers is very low due to low potential for exposure.

9.2.5. Public health – risk characterisation

Public exposure to the notified chemical will occur from the use of personal care products containing the notified chemical. Exposure will be primarily via dermal contact, with minimal inhalation exposure and the possibility of accidental ocular exposure. The notified chemical is of low toxicity and will be used at low concentration in personal care products. Accidental ocular exposure may cause stinging and tearing, consistent with the known effects of irritant surfactants. However, the overall health risk arising from public exposure to the notified chemical 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 against the NOHSC Approved Criteria.

10.2. Environmental risk assessment

On the basis of the available information, the overall environmental risk is expected to be low.

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 Low 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 aqueous solution containing the notified 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 aqueous solution containing the notified 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

- Use the following safety phrase for products containing the notified chemical:
  S25 Avoid contact with the eyes

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  – Enclosed processes.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  – Impervious gloves and safety glasses or goggles.

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

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

- If products and mixtures containing EUCAROL AGE/SS 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 into the sewer or landfill.

Emergency procedures

Spills/release of the notified chemical should be contained as described in the MSDS (ie. covered with inert material and transfer to a sealable waste container) and the resulting waste disposed of in landfill.

Secondary notification

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

Under subsection 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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