File No.: NA/604

September 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Akypo-Soft 45NV

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Director
Chemicals Notification and Assessment

Akypo-Soft 45NV

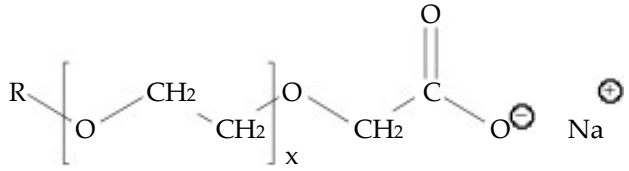
1. APPLICANT

Schwarzkopf Pty Ltd of 20 Rodborough Road FRENCHS FOREST NSW 2086 has submitted a limited notification statement in support of their application for an assessment certificate for Akypo-Soft 45NV.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	poly(oxy-1,2-ethanediyl), a-(carboxymethyl)-w-(dodecyloxy)-, sodium salt
Other Names:	sodium laureth-6 carboxylate Akypo-Soft 45NV (22% notified chemical) Akypo RLM 45N (22% notified chemical
Product Name:	Napro LiveColour (contains 2.475% Akypo-Soft 45NV; [a] 0.54% notified chemical)
Chemical Abstracts Service (CAS) Registry No.:	33939-64-9
Molecular Formula:	$(C_2H_4O)_nC_{14}H_{28}O_3.Na$

Structural Formula:



R = $C_{12}H_{25}$ n=12 x=4 or 5

Molecular Weight:	442-487
Method of Detection and Determination:	the notified chemical was identified by infrared (IR) spectroscopy
Spectral Data:	major characteristic IR peaks identified at the following wavelengths: 2 924, 2 854, 1 732, 1 610, 1 464, 1 350, 1 249, 1 118, 1 042, 949 and 856 cm^{-1}

Comments on Chemical Identity

Data from infra-red spectroscopy have been provided for the chemical. The structural formula for the notified chemical indicates that the alkyl chain length ranges from 10-16 carbon atoms. However, the CAS number given corresponds only to the 12 carbon homologue. It is noted that the poly(oxy-1,2-ethanediyl), -(carboxymethyl)-(dodecyloxy)-, compound with chitosan (a complex carbohydrate that is derived from D-glucosamine) is listed on the Australian Inventory of Chemical Substances (AICS). The inventory also contains the sodium salts of some higher homologues: poly(oxy-1,2-ethanediyl), -(carboxymethyl)-(tridecyloxy)-, sodium salt [$(C_2H_4O)_nC_{15}H_{30}O_3.Na$]; poly(oxy-1,2-ethanediyl), -(carboxymethyl)-(tetradecyloxy)-, sodium salt [$(C_2H_4O)_nC_{16}H_{32}O_3.Na$]; and poly(oxy-1,2-ethanediyl), -(carboxymethyl)--(hexadecyloxy)-, sodium salt [$(C_2H_4O)_nC_{18}H_{36}O_3.Na$].

3. PHYSICAL AND CHEMICAL PROPERTIES

The following physical and chemical properties unless specified otherwise are for the product containing the notified chemical at approximately 0.54%

Appearance at 20°C and 101.3 kPa:	clear yellow liquid
Boiling Point:	100°C (water)
Density:	1000 $kg.m^{-3}$ (water)
Vapour Pressure:	2.39 kPa at 20°C
Water Solubility:	$\geq$ 5 000 $mg.L^{-1}$ (see comments below)
Partition Co-efficient (n-octanol/water):	not determined (see comments below)
Hydrolysis as a Function of pH:	not determined (see comments below)
Adsorption/Desorption:	not determined (see comments below)

Dissociation Constant:	not determined (see comments below)
Flash Point:	not determined (the notified chemical is imported as an aqueous solution)
Flammability Limits:	not flammable
Flammability Limits:	not determined
Autoignition Temperature:	not determined
Explosive Properties:	not explosive
Reactivity/Stability	not reactive

Comments on Physico-Chemical Properties

The water solubility of the chemical has not been determined to saturation point. However, in the ecotoxicity studies stock solutions of up to 5,000 $mg.L^{-1}$ were prepared without any undissolved material being observed.

The hydrolytic behaviour of the chemical has not been investigated. The chemical contains no functional groups that are likely to be susceptible to hydrolysis within the environmental pH range (4-9).

The notifier indicates that the notified chemical is a surfactant and a reliable partition coefficient cannot be determined. Based on its high solubility the chemical is likely to have a low octanol/water partition coefficient (Log P_{ow}) but this may be offset by its surface activity, which would also affect the measurement of partition coefficient.

No data were provided for the adsorption/desorption behaviour of the notified chemical. Again based on the high water solubility and expected low partition coefficient, the chemical should not bind strongly to the organic matter in the soil and may potentially be mobile. However, any surface activity would increase the binding of the chemical to soils and sediments.

The notified chemical contains a carboxylate functionality that is expected to have typical basicity. The conjugate carboxylic acid form of the notified chemical is expected to display typical acidity.

4. PURITY OF THE CHEMICAL

Degree of Purity: $\geq$ 99%

Hazardous Impurities:

The chemicals are below listed on National Occupational Health and Safety Commission (NOHSC) *List of Designated Hazardous Substances* (). They are not hazardous substances at the concentrations below. The health effts risk phrases from NOHSC are include.

Chemical name:	monochloroacetic acid
CAS No.:	79-11-8
Weight percentage:	≤ 0.002%
Toxic properties;	toxic by inhalation, in contact with skin and if swallowed; causes severe burns (R23/24/25; R35)

Chemical name:	1,4-dioxane
CAS No.:	123-91-1
Weight percentage:	< 0.0001%
Toxic properties;	irritating to eyes and respiratory system; possible risk of irreversible effects (carcinogen) (R36/37; R40(3))

Chemical name:	ethylene oxide
CAS No.:	75-21-8
Weight percentage:	< 0.0001%
Toxic properties;	toxic by irritation; irritating to eyes, respiratory system and skin; may cause cancer; may cause heritable genetic damage (R23; R36/37/38; R45(2); R46(2))

Non Hazardous Impurities:

Chemical name:	sodium chloride
CAS No.:	7647-14-5
Weight percentage:	≤ 0.5 %

Additives/Adjuvants:

Chemical name:	water
CAS No.:	7732-18-5
Weight percentage:	≤ 78.5 %

Chemical name:	Euxyl K 400[1]
CAS No.:	none allocated
Weight percentage:	≤ 0.05 %

[1]methyl dibromoglutaronitril / phenoxyethanol / polyquaterium-7

Chemical name:	Phenonip[2]
CAS No.:	non-allocated
Weight percentage:	≤ 0.5 %

[2]phenoxyethanol / methyl paraben / ethyl paraben / propyl paraben / butyl paraben

4. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It is a thickener for surfactant based formulations such as hair dyes. It will be imported in a ready-to-use liquid formulation, as a surfactant in a hair colour altering preparation called Napro LiveColour.

Napro LiveColour typically contains 0.54% by weight of the notified chemical.

It is estimated that approximately 5 tonnes per annum of the notified chemical will be imported in the first five years.

6. OCCUPATIONAL EXPOSURE

Napro Livecolour will be imported ready-to-use, in 50 mL plastic bottles contained in an outer cardboard box. The product will be transported from the dockside to the notifier's warehouse for storage, prior to distribution to supermarkets nationwide.

Waterside workers, transport drivers, warehouse and supermarket workers will handle the product but could only be exposed to the notified chemical in the event of an accident.

The notifier estimates that up to 1% of the notified chemical may be accidentally spilt within the warehouse.

The notifier suggests that the imported product containing the notified chemical would not be used by professional hairdressers. Irrespective of whoever users the product, gloves are included in the package according to the product label.

7. PUBLIC EXPOSURE

In case of accidental spillage, the spillage should be contained with absorbent material such as sand or vermiculite and the waste should be disposed of in accordance with Local, State and Federal regulations.

Accidental spills may occur at the warehouse and it is estimated that up

8. ENVIRONMENTAL EXPOSURE

Release

The notifier estimates that up to 1% (50 kg) of the notified chemical may be lost through accidental spills at warehouses. The imported product, Napro LiveColour, containing the notified chemical is expected to be used in bathrooms and other

wet areas throughout Australia. The majority of the product is expected to enter the sewers from these wet areas and to be treated with the sewage before being released to the environment.

The notifier estimates that up to 2% of the notified product may remain in the bottle after use. This equates to a maximum of 100 kg per annum which will be consigned to landfill via domestic garbage

Fate

The notifier has provided a study on the biodegradation of the notified chemical (). The biodegradation of the chemical was investigated using the modified OECD screening test (OECD guideline 301E). Over a period of 19 days the chemical was degraded by 96%, as determined by a reduction in the bismuth-active substance (BiAS) level in the test medium. The BiAS level measures the amount of nonionic surfactants containing polyethylene oxide (). While this does not meet the OECD criteria for "readily biodegradable", as the loss of the parent compound is measured and not mineralisation, degradation may be expected in the aquatic environment.

Akypo-Soft 45NV is thickner for a surfactant based liquid hair colour. It would be expected to be released to the environment via consumer use through rinsing the chemical off the hair and into the sewerage system. In the sewer, it is anticipated that some would adsorb to sewage sludge due to the expected surface active nature of the chemical. The sludge will either be consigned to landfill or incinerated. Incineration products include water and oxides of carbon and nitrogen. The remainder will stay in solution, where it is expected that it will be further diluted and degraded.

The high water solubility and biodegradable nature of the notified chemical indicate that it is unlikely that it will bioaccumulate ().

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicities of Akypo Soft 45NV (22% notified chemical) and Akypo RLM 45N (22%)

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} >2 000 $mg.kg^{-1}$	()
skin irritation	rabbit	slight irritant	()
eye irritation	rabbit	severe irritant	()
skin sensitisation	guinea pig	non-sensitiser	()

9.1.1 Oral Toxicity (ref)

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Test Substance:	Akypo RLM 45N
Method of administration:	a single dose of 2 000 $mg.kg^{-1}$ of Akypo RLM administered by gavage; vehicle was arachis oil BP (concentration not specified)
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (ref) >
LD_{50}:	2 000 $mg.kg^{-1}$
Result:	by implication, the notified chemical was of low acute toxicity when administered orally in a limit test in rats

9.1.2 Skin Irritation (Ref)

Species/strain:	rabbit/Himalayan
Number/sex of animals:	3 males
Observation period:	up to 4 days
Test Substance:	Akypo-Soft 45NV (as supplied, 21% notified chemical)
Method of administration:	0.5 ml of the test substance was applied to intact skin for 4 hours

Draize scores (ref):

Time after treatment (days)	***Animal #***			
	1	***2***	***3***	***4***
Erythema [i]				
1	0	1	1	0
2	0	0	0	0
3	0	1	1	0
Oedema				
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0

[i] see Attachment 1 for Draize scales

Test method: similar to OECD guidelines (ref)

Result: the test substance was a slight skin irritant in rabbits

9.1.3 Eye Irritation (ref)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 females

Observation period: up to 11 days

Test Substance: Akypo-Soft 45NV (as supplied, 21% notified chemical

Method of administration: 0.1 mL of the test substance was placed in the conjunctival sac of the right eye of each rabbit

Draize scores ( ) of unirrigated eyes:

	Time after instillation														
Animal	***1 hour***			***24 hours***			***48 hourss***			***72 hous***			***11 days***		
Cornea															
1	0[1]			0			0			0			0		
2	1			1			1			1			1		
3	1			1			1			1			1		
Iris															
1	0			1			1			1			1		
2	0			1			1			1			1		
3	0			0			0			0			0		
Conjunctiva	***r[c]***	***C[d]***	***d[e]***	***R[c]***	***c[d]***	***d[e]***	***r[c]***	***C[d]***	***d[e]***	***R[c]***	***C[d]***	***d[e]***	***R[c]***	***C[d]***	***d[e]***
1	0	0	3	1	0	3	1	0	3	1	0	3	0	0	
2	0	0	3	1	1	3	1	1	3	1	1	3	0	0	
3	0	0	3	1	1	3	1	1	3	1	1	3	0	0	

[1] see Attachment 1 for Draize scales [c] redness [d] chemosis [e] discharge

Test method: similar to OECD guidelines (ref)

Result: the test substance containing 21% notified chemical was a severe eye irritant in rabbits

9.1.4 Skin Sensitisation

Species/strain: guinea pig/Dunkin Hartley

Number of animals: 10 males (test group), 5 males (control group)

Test Substance; Akypo-Soft 45NV

Induction procedure: Day 0
each animal received 2 intracutaneous injections (0.1 mL) in the scapular region:

- Freund's Complete Adjuvant (FCA), 1:1 with 0.9% saline
- The test substance (undiluted)
- The test substance in a 1:1 mixture of FCA

Day 7
the same region was treated with 2 mL of the test substance (undiluted) using the patch-test technique for 48 hours

Challenge procedure: Day 21
the left flank of each animal was treated with 2 mL of solution (0.8% aqueous hydroxypropylmethyl cellulose gel) containing the test substance (0.01%) under occlusive dressing for 24 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
0.01%	0/10**	0/10	0/5	0/5

* time after patch removal
** number of animals exhibiting positive response

Test method: similar to OECD guidelines (ref)

Result: by implication, the notified chemical was not a sensitiser to the skin of guinea pigs

9.2 Repeat Dose Toxicity

9.2.1 90-Day Repeat Dose Oral toxicity Study (based on analog data of sodium lauryl sulphate and sodium lauryl ethoxysulphate)()

Species/strain: rat/*Carworth Farm 'E'*

Number/sex of animals: 228/sex
12/sex/group in all dose groups;
18/sex/group in control groups

Method of administration: test substance incorporated in the chew diet

Dose/Study duration: the test substance was administered daily in the diet for a period of 13 weeks :

control	0 ppm
low dose	40 ppm
low-mid dose	200 ppm
mid dose	1 000 ppm
high dose	5 000 ppm

	all animals were sacrificed at the end of the treatment period (13 weeks)
Clinical observations:	no adverse clinical effects on the animals were noted in the study
Clinical chemistry/Haematology	increase in serum urea concentration in females receiving 5 000 ppm of sodium lauryl sulphate; however, serum protein fractions remained unaffected
Gross Pathology:	increase in liver, kidney and spleen weights were noted at 5 000 ppm in females
Test method:	(ref)
Result:	the organ weights and blood chemistry effects observed were unaccompanied by any pathological changes; the authors considered that 1 000 ppm would be a "no-effect" dietary level for both test substances

9.2.2 Two-Year Repeat Dose Oral toxicity Study (based on analog data of sodium lauryl glyceryl ether sulphanate and sodium lauryl trioxyethylene sulphate)()

Species/strain:	rat/*Carworth Farm 'E'*
Number/sex of animals:	150/sex 30/sex/group; in the control and all dose groups
Method of administration:	test substance incorporated in the diet
Dose/Study duration:	each group received 0.1% or 0.5% of the test substance daily in th diet for a period of 105 weeks; 10 animals of each group were sacrificed at 52 weeks and the rest at 105 weeks
Gross Observations:	no differences in appearance or behaviour among treated and control animals; no differences in gross pathology
Clinical observations:	no adverse effects on clinical conditions of the animals were noted in the study

Clinical chemistry/Haematology	no effects on haematological profile or clinical chemistry parameters
Histopathology:	no treatment-related microscopic effects; isolated instances of significant changes in organ:body weight in the experimental groups could not be related to microscopic changes and were not considered biologically important
Test method:	(ref)
Result:	no adverse effects were observed in the animals with respect to survival, growth, food consumption, hematologic values, blood chemistry and urine analysis

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (ref)

Strains:	*Salmonella typhimurium* TA 1538 TA 1537, TA 1535, TA 100 and TA 98
Concentration range:	the assay was performed in two independent experiments with or without S9 metabolic activation; the test substance and controls were tested in triplicate at the following concentrations: 312.5, 625, 1 250, 2 500 5 000 m g/plate
Test Substance:	Akypo-Soft 45NV
Test method:	similar to OECD guidelines (ref)
Result:	the test substance was not toxic towards the tester stains at 5 000 mg/plate; there were no significant increases in revertant colony numbers at any dose level, either in the presence or absence of metabolic activation; by implication, the notified chemical is not considered to be mutagenic in bacteria

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (based on analog data of linear alkylbenzene)(ref)

Species/strain:	mouse/ICR
Number animals:	all females whose fertilization was established were used for the study; 6/group for control and test groups dosed on day 3 of gestation; 7/group for positive control group dosed on day 3 of gestation and all dosed groups on day 17 of gestation
Doses:	0, 1, 2 and 10 mg/mouse; negative control water (0.1 mL/mouse) and saline (0.5 mL/mouse); positive control mitomicyn C (2 mg/kg)
Method of administration:	experiment 1: on day 3 of gestation LAS was administered in a single oral dose of 2 mg/mouse and on day 18 of gestation each animal was sacrified experiment 2:on day 17 of gestation each animal received a subcutaneous dose of 1, 2 or 10 mg/mouse and on day 18 of gestation each animal was sacrificed
Test method:	the micronucleus test by W Schmid ()
Result:	there was no difference among treated groups in the incidence of polychromatic erythrocytes with micronuclei in the maternal bone marrow and the fetal liver and blood not clastogenic in mouse bone marrow cells *in vivo*

9.4 Overall Assessment of Toxicological Data

By implication, the notified chemical has low acute oral toxicity (LD_{50} > 5 000 $mg.kg^{-1}$) in rats. Similarly, it is likely to be a slight skin irritant and a severe eye irritant in rabbits but not a skin sensitiser in guinea pigs.

A 90-day feeding study based on analog data showed 1 000 ppm to be a “no-effect” dietary level. A 2 year feeding study is also based on analog data showed no signs of organ toxicity or irreversible effects.

By implication, the notified chemical is found not to be mutagenic by

bacterial reverse mutation. No induction of micronuclei was observed in bone marrow cells of the mouse.

According to the *Approved Criteria for Classifying Hazardous Substances* (), Akypo-Soft 45NV containing 22% of the notified chemical would be classified as hazardous, in relation to irritant effects (eye). As Akypo-Soft 45NV is largely composed of notified chemical (22%) and water (78%) it is highly likely that the eye irritation effects are derived from the notified chemical. Substances containing the notified chemical or Akypo-Soft 45 NV at 20% would require R36 irritating to eyes, on this basis Napro LiveColour would not require R36, as Akypo-Soft 45NV is present below the cut off concentration.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies were supplied by the notifier. The tests were carried out according to OECD Test Methods.

Species	Test	Concentrations [a] ($mg.L^{-1}$)	Result ($mg.L^{-1}$)	Reference
Rainbow trout *(Oncorhynchus mykiss)*	96 h acute	10, 18, 32, 56, 100	$10 < LC_{50} < 18$ [b] NOEC = 10	()
Ide *(Leuciscus idus melantous)*	96 h static acute	1, 2, 3, 4	$LC_{50} = 2.64$[c] (CI 2.04-3.33)	()
Water Flea (*Daphnia magna*)	48 h acute	0, 1, 2, 4, 8, 16, 32, 64, 132	$4 < EC_{50} < 8$[d] NOEC £ 0.5	()

[a] Nominal concentrations. [b]Concentration resulting in 0 and 100% mortality. [c]Calculated by Environment Australia using probit analysis. [d]Concentration resulting in 0% and 100% immobility.

In the rainbow trout study 100% mortality was observed at concentrations of 18 $mg.L^{-1}$ and above after 24 h. At 56 $mg.L^{-1}$ 100% mortality was observed after 3 h. At 32 $mg.L^{-1}$ after 6 h 605 mortality was observed, rising to 100% by 24 h. No mortality was observed at 10 $mg.L^{-1}$. Hence, the 96 h LC_{50} lies between 10 and 18 $mg.L^{-1}$. A more accurate estimate, such as by the use of probit analysis, is precluded as mortality between 0 and 100% is not observed.

In the fish study, 40% and 30% mortality was observed at 2 $mg.L^{-1}$ and 3 $mg.L^{-1}$ test levels, respectively after 96 h. 100% mortality was observed at the highest test level after 48 h. Probit analysis of the 96 h data gave an LC_{50} of 2.64 (95% confidence interval 2.04-3.33 $mg.L^{-1}$).

At concentrations of 32 $mg.L^{-1}$ and above, 100% immobilisation was observed after 24 in the daphnia test. No immobilisation was observed at < 4 $mg.L^{-1}$. After 24 h,

50% immobilisation was observed at 2 $mg.L^{-1}$; this increased to 100% by 48 h. At 1 $mg.L^{-1}$, 40% immobilisation was observed after 48 h. Hence, the EC_{50} is between 4 and 8 $mg.L^{-1}$. Once again, a more accurate estimate such as by the use of probit analysis is precluded, as immobilisation between 0 and 100% was only observed at one concentration.

No ecotoxicity data have been provided for algae and chronic exposure to Daphnia. These are required under the Act. The notifier has sought a variation of the schedule data requirements for algae on the grounds of diffuse exposure and the biodegradability of the chemical. In response, the release of the chemical will be diffuse, and this coupled with the biodegradability of the chemical, would suggest that the chemical, is unlikely to exhibit chronic toxicity in the environment. However, a full ecotoxicity profile as required under the Act should be provided if the event of a significant increase in the exposure to the aquatic compartment to the chemical occurs.

The provided ecotoxicity data for the notified chemical indicate that chemical is moderately toxic to both fish and daphnia.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The vast majority of notified polymer will be discharged to sewer through product use. The notifier has provided predicted environmental concentrations (PECs) of 4.4 ppb and 0.11 ppm for the discharge of a single use into a metropolitan and country sewer, respectively. In Environment Australia's view these concentrations represent an overestimate and are based on incorrect assumptions such as dilution rates which do not take into account the true volume of water used each day [~150 L per person per day is a conservative estimate (EC 1994)].

As the product may used nation wide, and sent to sewage treatment plants in both city and country locations, a PEC based on continental use has been calculated:

Import Volume per annum	4,850 kg
Amount discharged to sewer	100%
Volume discharged per day	13.3 kg
Sewer output per day*	2 700 ML
Concentration in Sewage Treatment Plant	4.9 m $g.L^{-1}$ (ppb)

*Sewer output based on an Australian population of 18 million, each using 150 L water per day.

The low level in the imported product, its widespread use, and the resultant low concentration of the chemical in surface waters (well below the estimated toxicities for fish and daphnia) indicates that the overall environmental hazard of the notified chemical can be rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical will be imported as a liquid formulation in a ready-to-use form for the retail market.

Based on the toxicological data, the notified chemical is not expected to exhibit acute oral toxicity and is not likely to be genotoxic. It is a slight skin and severe eye irritant. The notified chemical is classified as a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances* () on the basis of eye irritation. The cut-off concentration for eye irritation is $\geq$ 25%. The imported retail product contains the notified chemical at a concentration of 0.5% by weight and is not a hazardous substance in relation to the notified chemical.

The occupational risk posed to waterside, transport, warehouse and supermarket workers is negligible. The notifier has indicated some spillage of the product within the warehouse. However overall the risk to these workers would be low because of the anticipated low health hazard of the imported formulation. No other mode of occupational exposure to the notified chemical is anticipated. The product is imported in a ready-to-use form and the notifier has suggested (but not completely ruled out) that the product would not be used by professional hairdressers.

13. RECOMMENDATIONS

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

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the product containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (ref).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. National Occupational Health and Safety Commission 1994, *List of Designated Hazardous Substances* [NOHSC:10005(1994)], Australian Government Publishing Service Publ., Canberra.

2. Hilverkus U (1992) Test for ready biodegradability (screening test). Report No. not specified, Study not specified, Sample designation Akypo RLM 45, MB number V 8857, FB Number 63073. Chemische und Biologische Laboratien GmbH, Institut Fresenius, Taunusstein, Neuhof, Germany. Unpublished.

3. Holt MS (1992) *The environmental Chemistry, fate and effects of nonionic-surfactants*, pp 90-144. In, Hutzinger, O. & de Oude, N.T. (eds), Handbook of Environmental Chemistry, Vol 3: Part F, Anthropogenic Compounds: Detergents, Springer-Verlag, Berlin.

4. Connell DW (1989) General characteristics of organic compounds which exhibit bioaccumulation. In: Connell DW ed, Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

5. Hempstock, J.B.J. 1996, *Acute Oral Toxicity Study with Akypo RLM 45N in rats*, Project no., 140/511, Safepharm Laboratories Ltd., Derby. UK.

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

7. Leuschner, P.J. 1995, *Primary Skin Irritation Study with Akypo RLM 45N in Rabbits*, Project no., 9000a/94, Laboratory of Pharmacology and Toxicology, Hamburg, Germany.

8. Draize, J.H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, vol. 49, pp. 2-56.

9. Leuschner, P.J. 1995, *Primary Eye Irritation Study with Akypo RLM 45N in Rabbits*, Project no., 8999a/94, Hamburg, Germany..

10. Leuschner, P.J. 1995, *Contact Hypersensitivity to Akypo RLM 45N in Albino Guinea Pigs - Maximisation Test*, Project no., 8833a/94, Hamburg, Germany.

11. Walker, A.I.T., Brown, V.K.H., Ferrigan, L.W., Pickering, R.G., and Williams, D.A., *Toxicity of Sodium Lauryl Sulphate, Sodium Lauryl Ethoxysulphate and Corresponding Surfactants Derived from Synthetic Alcohols,* Tunstall Laboratory "Shell" Research Ltd., Sittingbourna, Kent, England, Fd Cosmet. Toxocol., vol , 157-165 (may/June 1979)

12. Tusing, T.W., Paynier, O.E., Opdyke, D.L., and Snyder, F.H., *Toxicologic Studies on Sodium Lauryl Glyceryl Ether Sulphonate and Sodium Lauryl Trioxethylene SulphateHazleton* Laboratories, Falls Church, Virginia and Miami Valley Laboratories, Cincinnati Ohio, Toxicology and Applied Pharmacology, Vol 4, p 402-409, (1962).

13. Pateman, J.R., Biol, C., Biol, M.I., 1994, *Salmonella Typhimurium Reverse Mutation Assay with Akypo RLM 45N*, Project no., 590/23, Safepharm Laboratories Ltd., Derby. UK.

14. Koizumi, N., Ninomiya, R., Inoue, Y., Tsukamoto, T., Fujii, M., and Yamamoto, Y., *Implantation Disturbance Studies with Linear Alkylbenzene Sulphonate in Mice.* Arch. Environ. Contam. Toxicol. Vol 14, p 73-81 (1985).

15. Black, J.G. and Howes, D., *Skin Penetration of Chemically Related Detergents*, Environmetal Safety Division, Unilever Research, Colworth Laboratory, Bedford, England, *J. Soc. Cosmet. Chem.,* 30, 157-165 (1979).

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

17. Wetton PM (1996) Akypo RLM 45N: *Acute toxicity to Rainbow trout* (*Oncorhynchus mykiss*). SPL Project Number 140/451, Safepharm laboratories Limited, Derby, U.K. Unpublished.

18. Hilverkus U (1991a) Test for Acute toxicity on fish. Report No. not specified, Study not specified, Sample designation Akypo RLM 45, MB number V 8515, FB Number 680001. Chemische und Biologische Laboratien GmbH, Institut Fresenius, Taunusstein, Neuhof, Germany. Unpublished.

19. Hilverkus U (1991b) Test for Acute toxicity on daphnia. Report No. not specified, *Study not specified, Sample designation Akypo RLM 45, MB number V 8515, FB Number 680001.* Chemische und Biologische Laboratien GmbH, Institut Fresenius, Taunusstein, Neuhof, Germany. Unpublished.

20. European Commission (1994) *Technical guidance documents in support of the commission regulation (EC) No. 1488/94 on risk assessment for existing substances in accordance with council regulation (EEC)* No. 793/93. European Commission , Brussels.

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

Attachment 1

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

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

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

CORNEA

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

CONJUNCTIVAE

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

IRIS

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