File No: NA/603

July 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Aminol A15

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Director
Chemicals Notification and Assessment

Aminol A15

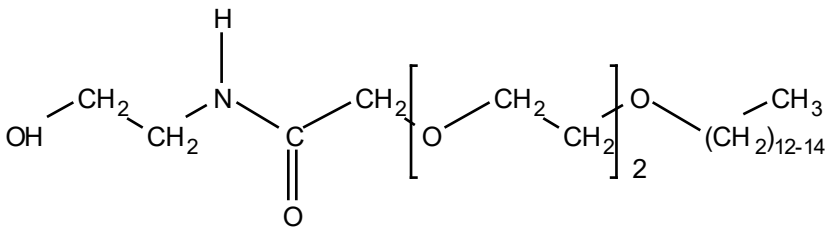
1. APPLICANT

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 Aminol A15.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	poly(oxy-1,2-ethanediyl), α-[2-[(2-ydroxyethyl)amino] -2-oxoethyl]-ω-hydroxy-, mono-C_{13-15}-alkyl ethers
Chemical Abstracts Service (CAS) Registry No.:	107628-04-6
Marketing Names:	Aminol A15
Product Name:	Napro LiveColour (contains ≤ 0.5% of the notified chemical)
Molecular Formula:	unspecified

Structural Formula:



Molecular Weight:	390-418
Method of Detection and Determination:	the notified chemical was separated by Gel Permeation Chromatography (GPC) and identified by infrared (IR) spectroscopy
Spectral Data:	major characteristic IR peaks identified at the following wavelengths: 1 115, 1 249, 1 347, 1 465, 1 542, 1 663, 2 854, 2 924 and 3 339 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

The following physical and chemical properties unless specified otherwise are for the product containing the notified chemical at a concentration of $\leq$ 0.5%.

Appearance at 20°C and 101.3 kPa:	clear yellow liquid
Boiling Point:	100°C (water)
Density:	100 kg/m^3 (water)
Vapour Pressure:	2.39 kPa at 20°C
Water Solubility:	not determined (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 product containing the notified chemical is not flammable
Flammability Limits:	not flammable (the product)
Autoignition Temperature:	not determined (the notified chemical is not expected to undergo auto ignition)
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, the ecotoxicity studies stock solution of 1 000 mg/L were prepared without any undissolved material being observed.

The hydrolytic behaviour of the chemical has not been investigated. The chemical contains an amide functional group which could potentially undergo hydrolysis. However, it is unlikely that this will occur within the environmental pH range (4-9).

The notifier indicates that the notified chemical is a non-ionic 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 but this may be offset by its surface activity, which would also effect the measurement of partition coefficient.

No data were provided for the adsorption/desorption behaviour of the notified chemical. 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 notified chemical to soils and sediments.

The notified chemical contains no functional groups which would be protonated or deprotonated in the environmental pH range (4-9).

4. PURITY OF THE CHEMICAL

Degree of Purity: > 96%

Toxic or Hazardous Impurities:

Chemical name:	monoethanolamine
CAS No.:	141-43-5
Weight percentage:	0.5%
Toxic properties:	irritating to skin, eye and respiratory system; harmful by inhalation according to the NOHSC List of Designated Hazardous Substance (1)

Monoethanolamine is not a hazardous substance at the concentration present within the notified chemical.

Other Impurities:

Chemical name:	water
Weight percentage:	3.5%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. Aminol A15 will be imported in a ready-to-use liquid formulation, as a surfactant in a hair colour altering, liquid preparation.

The notified chemical will be imported as a component of Napro LiveColour, which typically contains approximately 0.5% by weight of Aminol A15. No information is provided on the other ingredients in the product.

It is estimated that 750 kg per annum of the notified chemical will be imported in the first five years.

6. OCCUPATIONAL EXPOSURE

The product containing the notified chemical (0.5%) will be imported in a ready-to-use form for the retail market, 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.

It is anticipated that waterside workers, transport drivers, warehouse and supermarket workers would only be exposed to the notified chemical in the event of an accident.

The submission does not indicate whether or not the product will be used by professional hairdressers. The product label states that gloves are included in the package.

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 to 7.5 kg/year of the notified chemical will be released in this way. The spillage would be collected and disposed of in accordance with the Local, State and Federal regulations.

The notified chemical will enter the public domain as a hair dye product. It is expected that the product would be applied every 4 to 6 weeks. Although public contact will occur during use, exposure would be minimised by the low concentration of the notified chemical in the

product (≤ 0.5%), intermittent use and washing of the excess dye out of the hair following application. A small quantity of the volume (2%, approximately 15 kg/year) will remain in the bottle after emptying and will be disposed of to landfill via domestic garbage collection. The remaining notified chemical (727.5 kg/year) will be released to domestic sewer systems when excess dye is washed out of the hair.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier estimates that up to 1% (7.5 kg) of the notified chemical may be lost. 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 15 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 (2), although this is not required under the Act. 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 79%, 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 (3). While this does not meet the OECD criteria for "readily biodegradable", as only the loss of the parent compound is measured not mineralisation, degradation may be expected in the aquatic environment.

Aminol A15 is a surfactant in a liquid hair colour and, as such, 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 will 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 the chemical will bioaccumulate (4).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Aminol A15

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} >5 000 mg/kg	(5)
skin irritation	rabbit	Severe irritant	(7)
eye irritation	rabbit	Slight to moderate irritant	(9)

9.1.1 Oral Toxicity (5)

Species/strain: rat/Sprague Dawley

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: a single dose of 5 000 mg/kg administered by gavage; vehicle was 0.25% aqueous solution of gum tragacanth

Clinical observations: none

Mortality: none

Morphological findings: none

Test method: similar to OECD guidelines (6)

LD_{50}: > 5 000 mg/kg

Result: the notified chemical was of low acute toxicity when administered orally in a limit test in rats

9.1.2 Skin Irritation (7)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 females

Observation period: 21 days

Method of administration: 0.5 mL of the notified chemical applied to intact skin for 4 hours

Draize scores (8):

Animal #	*Time after treatment (days)*					
	1	*2*	*3*	*7*	*14*	*21*
Erythema	[I]					
1	2	4	4	1	1	1
2	1	3	4	4	1	1
3	2	4	4	4	1	1
Oedema						
1	3	4	4	1	1	1
2	3	4	4	3	1	0
3	3	4	4	3	1	1

[i] see Attachment 1 for Draize scales

Test method: similar to OECD guidelines (6)

Result: the notified chemical was a severe skin irritant in rabbits

9.1.3 Eye Irritation (9)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 females

Observation period: 7 days

Method of administration: 0.1 mL of the notified chemical was placed in the conjunctival sac of the left eye of each rabbit

Draize scores (8) of unirrigated eyes:

	Time after instillation														
Animal	***1 hour***			***1 days***			***2 days***			***3 days***			***7 days***		
Cornea															
1	0[1]			0			0			0			0		
2	0			0			0			0			0		
3	0			0			0			0			0		
Iris															
1	1			0			0			0			0		
2	1			0			0			0			0		
3	1			0			0			0			0		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	2	1	2	1	1	2	1	1	1	0	0	0	0	0
2	1	2	1	2	1	1	2	1	1	2	0	0	0	0	0
3	2	2	1	2	1	1	2	1	2	2	1	1	0	0	0

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

Test method: similar to OECD guidelines (6)

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

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (10)

Strains: *Salmonella typhimurium* TA 1537, TA 1535, TA 100 and TA 98

Concentration range: the assay was performed in two independent experiments with or without metabolic activation provided by rat liver S9; the test substance and controls were tested in triplicate at the following concentrations: 8, 40, 200, 1 000 and 5 000 µg/plate

Test method: similar to OECD guidelines (6)

Result: the notified chemical was not toxic towards the tester strains at 5 000 µg/plate; there were no significant increases in revertant colony numbers at any dose level, either in the presence or absence of metabolic activation;

the notified chemical is not considered to be mutagenic in bacteria

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute toxicity (LD_{50} > 5 000 mg/kg) in rats by oral administration. The notified chemical was a severe skin irritant and a slight to moderate eye irritant in rabbits.

The notified chemical was found not to be mutagenic by bacterial reverse mutation

According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (11), the notified chemical would be classified as hazardous, in relation to irritant effects (skin). Substances containing the notified chemical at ≥ 20% would be determined to be hazardous.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

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

Species	Test	Concentrations ($mg.L^{-1}$)	Result ($mg.L^{-1}$)	Reference
Ide *(Leuciscus idus melantous)*	96 h static acute	2, 3, 4	$2 < LC_{50} < 4$ NOEC ≤ 1	(12)
Water Flea (*Daphnia magna*)	48 h acute	0, 0.125, 0.25, 0.5, 1, 2, 4, 8, 16	$0.5 < EC_{50} < 2$ NOEC ≤ 0.5	(13)

[a] Nominal concentrations.

In the fish study, 20% mortality was observed at the 2 and 3 mg/L test level after 96 h and 100% mortality was observed at the highest test level after 24 h. Hence the LC_{50} is likely to be between 2 and 4 mg/L, but a more accurate estimate, such as by use of probit analysis, is precluded due to a lack of control data.

At concentrations of ≥ 4 mg/L, 100% immobilisation was observed after 24 in the daphnia test. No immobilisation was observed at ≤ 0.5 mg/L. After 24 h, 50% immobilisation was observed at 2 mg/L; this increased to 100% by 48 h. At 1 mg/L, 40% immobilisation was observed after 48 h. Hence, the EC_{50} is between 0.5 and 2 mg/L. Once again, a more accurate estimate such as by use of probit analysis, is precluded as immobilisation between 0 and 100% was only observed at one concentration.

The 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 4.1 ppb and 0.10 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 for 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 (14)].

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

Import Volume per annum	727.5 kg
Amount discharged to sewer	100%
Volume discharged per day	2.0 kg
Sewer output per day*	2 700 ML
Concentration in Sewage Treatment Plant	0.74 µg/L (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 supplied, the notified chemical is not expected to exhibit acute oral toxicity, and is not likely to be genotoxic. However, it is a severe skin and slight to moderate eye irritant. The notified chemical is classified as hazardous according to the NOHSC Approved Criteria (11) on the basis of skin irritation. The cut-off concentration for skin irritation is $\geq$ 20%. The imported product contains the notified chemical at 0.5% by weight so would not be classified as hazardous on this basis. The product Material Safety Data Sheet (MSDS) states that the product is not a hazardous substance.

The occupational risk posed to waterside, transport, warehouse and supermarket workers is considered negligible, given that there should be no exposure to the notified chemical under normal circumstances, and the anticipated low health hazard even if exposure to the imported product occurs accidentally. No other mode of occupational exposure to the notified chemical is anticipated prior to end use, since the product is imported in a ready-to-use form. The notifier does not suggest that the imported product containing the notified chemical would be used by professional hairdressers. However, if professional hairdressers did use the product, they would experience skin exposure and may be eye exposure. The product label warns that certain ingredients may cause skin irritation and that the product maybe injurious to the eye. These effects are not likely to relate to the concentration (0.5%) of notified chemical in the product.

No significant public exposure to the notified chemical is anticipated during transport. Members of the public will, however, make dermal and eye contact when using the product although exposure would be low because of the low concentration of the notified chemical in the product and the use pattern (intermittent use and washing off excess product after

application). Moreover, the label warns that the product may cause skin irritation to certain individuals and that a preliminary skin test should be made before use. The label states that gloves are enclosed and advises that the product should not be used for dyeing eyelashes or eyebrows.

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 MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (15).

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*

2. Hilverkus U (1992) Test for ready biodegradability (screening test). *Report No. not specified, Study not specified, Sample designation Aminol A 15, MB* Number V8855, FB Number 70226. 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. Meijer, H., Whittaker, C.J., 1986, *Study on the acute oral toxicity of Amino A15 in Sprague Dawley rats*, Project no., 250/8609, Toxicology Laboratories Limited, Herefordshire/England.

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

7. Pels Rijcken, W.R., 1991, *Study on the acute dermal irritation/corrosion of Aminol A15 in the rabbit*, Project no., 060918, RCC Notox B.V. Hambakenwetering 3, 5231 DD 's-Hertogenbosch, Netherlands.

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. Pels Rijcken, W.R., 1991, *Study on the acute eye irritation of Aminol A15 in the rabbit*, Project no., 060929, RCC Notox B.V., Hambakenwetering 3, 5231 DD 's-Hertogenbosch, Netherlands.

10. Asquith, J.C., Trenchard-Morgan, S. 1988, *On the study of Aminol A15 in the Ames test*, Project no., M/AMES/4143, Toxicology Laboratories Limited, Herefordshire/England.

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

12. Hilverkus U (1991a) Test for Acute toxicity on fish. Report No. not specified, *Study not specified, Sample designation Aminol A 15, MB number V 8517,* FB Number 68098. Chemische und Biologische Laboratien GmbH, Institut Fresenius, Taunusstein, Neuhof, Germany. Unpublished.

13. Hilverkus U (1991b) Test for Acute toxicity on daphnia. Report No. not specified, Study not specified, Sample designation Aminol A 15, MB Number V 8517, FB Number 68098. Chemische und Biologische Laboratien GmbH, Institut Fresenius, Taunusstein, Neuhof, Germany. Unpublished.

14. 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.

15. 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