File No: NA/592

May 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Amines, bis(hydrogenated tallow alkyl), oxidised

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Director
Chemicals Notification and Assessment

Amines, bis(hydrogenated tallow alkyl), oxidised

1. APPLICANT

Ciba Specialty Chemicals of 235 Settlement Road THOMASTOWN VIC 3074 has applied for the following information relating to 'Amines, bis(hydrogenated tallow alkyl), oxidised. No application for exempt information was submitted by the notifier and the report is published here in its entirety.

2. IDENTITY OF THE CHEMICAL

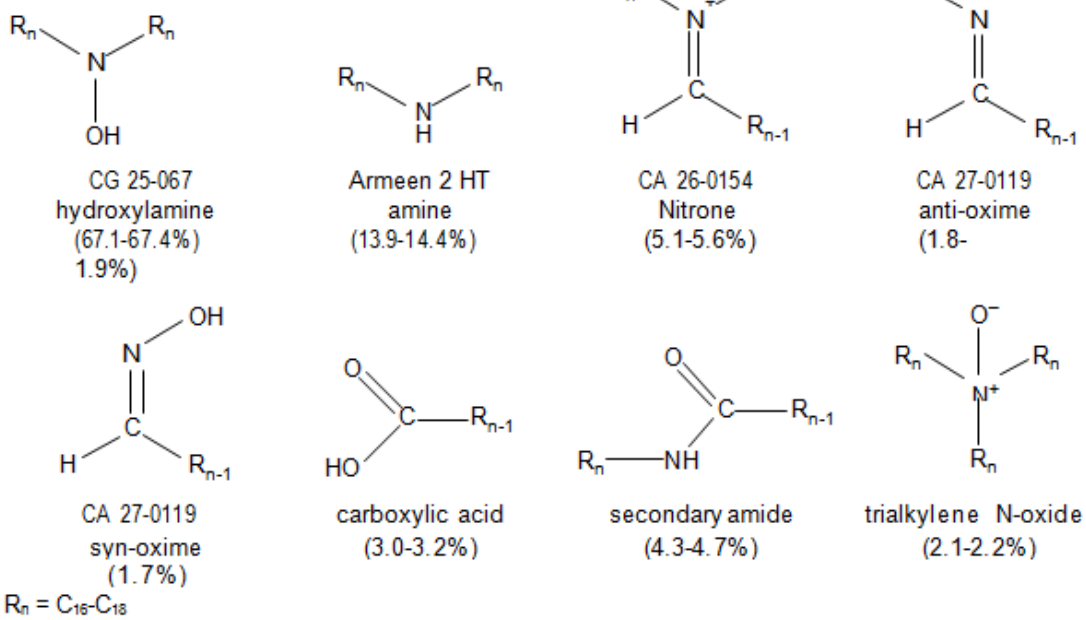
Chemical Name: amines, bis(hydrogenated tallow alkyl), oxidised

Chemical Abstracts Service (CAS) Registry No.: 143925-92-2

Trade Name: TKA 40082/CGA 042

Molecular Formula: $HON(R_n)_2$ where n = C_{16} to C_{18} is the main component in a mixture

Structural Formula:



Molecular Weight: range 481-538 (CG 25-067 main component)

Weight Percentage of Ingredients:	100%
Method of Detection and Determination:	data from ultraviolet/visible (UV/Vis) spectrophotometry, infrared (IR)and proton nuclear magnetic resonance spectroscopy (NMR) have been provided for the substance.

Comments on Chemical Identity

The notified chemical consists of a mixture of starting material and reaction products, all of which are considered to be part of the notified chemical by the notifier.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white off white solid, no odour
Melting Point:	56 - 92°C
Boiling Point:	> 280°C
Density:	0.95 at 23°C
Vapour Pressure:	3×10^{-12} kPa at 20°C 1×10^{-11} kPa at 25°C
Surface Tension:	70 $Nm.m^{-1}$ at 20°C
Water Solubility:	< 0.5 $mg.L^{-1}$ at 20°C
Partition Co-efficient (n-octanol/water):	log P_{ow} = 5.5 - 25 (calculated with CLOPG version 3.42; K_{ow} of respective components are: CG 25-067 (14.5); Armeen 2HT (11.4); CA 26-0154/7 (15.9); CA 27-0119/2 (7.3) carboxylic acid (5.5); secondary amide (14.8); trialkylene N-oxide (24.9)
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

Flammability Limits:	not flammable
Autoignition Temperature:	no self-ignition
Explosive Properties:	not considered an explosive; thermal, shock and friction sensitivity negative, however can form an explosive dust/air mixture
Reactivity/Stability:	not an oxidising agent

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

The water solubility was determined for the notified chemical using a visual test with a quantitation limit of 0.5 $mg.L^{-1}$. More sensitive alternative methods were not available due to the low solubility of the notified substance in common solvents and the lack of chromophores within the components.

The notifier indicated that the determination of the hydrolysis of the notified chemical was not performed due to the low solubility of the substance. The major components of the notified chemical (CG 25-067 and Armeen 2 HT) do not contain functional groups which are likely to be susceptible to hydrolysis. CA 26-0154, both CA 27-0119 and the secondary amide contain functional groups which could potentially hydrolyse. However given the low solubility and use of the notified chemical as a stabiliser for polyolefin plastics hydrolysis is not expected to occur.

Based on the low water solubility of the notified substance and the calculated values of the partition coefficients for the components, the individual constituents of the chemical would strongly adsorb to soils and sediments.

The amine starting material (Armeen 2 HT) is expected to have basicity typical of a secondary amine and would be expected to be partially protonated by the carboxylic acid component of the notified substance which is also expected to have typical acidity.

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 $mN.m^{-1}$ (1)

4. PURITY OF THE CHEMICAL

Degree of Purity: 100%

Toxic or Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight): none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported into Australia in 50 or 100 kg sturdy fibreboard boxes which have been designed for international transport. Import volumes for the notified substance are expected to be as follows:

Year	1	2	3	4	5
Import Volume (tonnes)	1-7	7-15	15-20	20	20

The notifier estimates that the notified substance will be formulated into masterbatches, containing less than 20% of the notified substance, at one industrial establishment in the Melbourne metropolitan area. Masterbatches will be transported to polymer producers in 50 or 100 kg sturdy fibreboard boxes.

Polyolefin fibres containing the notified substance (less than 0.1%) will be produced at up to three locations, one in New South Wales and two in Victoria. The polyolefin fibres have a wide range of applications including carpeting, carpet backing, fabrics, disposable nappies, disposable hospital gowns and packaging. Fibre spinning will occur at up to three other locations.

6. OCCUPATIONAL EXPOSURE

The notified chemical is imported as a component of a polymer stabiliser in sturdy polythene-lined fibre drums. Worker exposure during transport or handling is unlikely, unless an accidental spill occurs.

It is expected that up to three establishments in Australia may be involved in preparing masterbatches, a process where the notified chemical is added to the polymer blend. The batching operation consists of weighing out the granulated commercial product containing the notified chemical and addition to a blender. The weighing is carried out in a dispensary, equipped to handle very fine pigments and equipped with exhaust ventilation facilities. With these engineering controls in place, worker exposure is likely to be low, especially since the granulated forms of the notified chemical will minimise dusts that could come into contact with the

eyes, skin, and respiratory system of workers.

Once weighed, the additive containing the notifed chemical is taken to the dry powder blender and added to the polymer powder/granules. The addition to the blender is under the control of local exhaust or through a closed system of transfer, hence worker exposure during this phase of operations is also likely to be minimal. The blended masterbatch is discharged into a tote bin, usually via a closed transfer system or under the control of local exhaust ventilation and taken to melt processing equipment, such as fibre spinners. In melt processing equipment the granules are melted, extruded or moulded, and allowed to cool.

In the three establishments an estimated 95 plant operators and some 20 maintenance and laboratory technicians may be exposed to the notified chemical. However, much of this work would involve handling the cooled polymer fibers containing the notified chemical. As the notified chemical is encapsulated in the polymer matrix, exposure is likely to be negligible.

7. PUBLIC EXPOSURE

Although widespread public contact with fibres containing the notified chemical will occur, the notified chemical is encapsulated in the polymer matrix of polymer fibres in finished articles. Hence, exposure of the general public is likely to be negligible, especially since the notified chemical has extremely low water solubility and low vapour pressure, and the polymer fibres are resistant to degradation

8. ENVIRONMENTAL EXPOSURE

Release

Under normal conditions, the notified chemical would not be expected to be released during storage and transportation. The material safety data sheet (MSDS) contains adequate instructions for handling a spill should one occur.

Once empty the containers used to hold the notified substance will be disposed of to landfill. The notifier has estimated that there will be approximately 20 g of residual chemical left in these containers. This corresponds to a maximum of 8 kg of the notified chemical per annum at the maximum rate of import.

A master batch is a solid mixture of one or more compounds in a suitable carrier polymer. The concentration of the notified chemical in masterbatches is expected to be less than 20%. The process for formulating a master batch consists of weighing and blending of TKA 40082, polymer with other compounding ingredients. The blending is carried out in closed/sealed mixers. This pre-blending process is followed by a melting and extrusion process that completely dissolves and encapsulates the notified chemical into the polymer. Wastes from masterbatch formulation, consisting of dirty spilt material or purging material, are recycled.

Manufacturing of polyolefin fibres also takes place in a closed system. The masterbatches will be fed automatically in extrusion or moulding machinery from a hopper. Off spec material will be sold at cheaper prices and waste is expected to be minimal.

The notifier estimates that up to 5% waste may be generated by the fibre spinning process. This corresponds to a maximum of 1 tonne of the notified chemical per annum at the maximum rate of import. This material will be disposed of to landfill, bound within the polyolefin matrix.

Release to the environment of the notified chemical as a result of the generation of masterbatches and manufacturing of polyolefin fibres is expected to be minimal.

Fate

The substance was examined for biodegradation potential using EEC Directive 92/69, Part C.4-C (Modified Sturm Test), and OECD Test Guideline 301B. Over the 28 day test, biodegradation was less than 10%, indicating that TKA 40082 is not readily biodegradable under the conditions of the test.

The notified chemical contains a mixture of chemicals with molecular weights ranging from 256 to 790. The majority of these chemicals are non polar. The constituent chemical with lower molecular weights and which are non-polar have potential to bioaccumulate (2). However, any potential for bioaccumulation would be mitigated by the very low exposure to the aquatic compartment.

The notified chemical is intended for use as a stabiliser in polyolefin plastics. As such, the fate of the majority of the chemical will share the fate of the plastic articles into which it is incorporated. They will be disposed of to landfill or incineration at the end of their useful lifetimes. Incineration would destroy the chemical, and create typical decomposition products of water and oxides of carbon and nitrogen.

Around 1 tonne of the notified chemical will be disposed of to landfill as waste from empty containers or as waste from fibre spinning. Once bound within the polymer matrix, the chemical is not expected to be mobile. Only a small quantity (less than 5 kg per annum) of free chemical will be disposed of in this manner. Leaching of the chemical from landfill sites is not expected, due to the low water solubility of the notified chemical.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg.kg^{-1}	(3)
acute dermal toxicity	rat	LD_{50} > 2 000 mg.kg^{-1}	(4)
skin irritation	rabbit	slight irritant	(5)
eye irritation	rabbit	slight irritant	(6)
skin sensitisation	guinea pig	moderate sensitiser	(7)

9.1.1 Oral Toxicity (3)

Species/strain:	rat
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	the notified chemical given by gavage in oleum arachidis vehicle
Clinical observations:	all animals exhibited piloerection for a period of 24 hours following dosing
Mortality:	none
Morphological findings:	mottled thymus in male mice
Test method:	similar to OECD guidelines (limit test) (8)
LD_{50}:	> 2 000 mg.kg^{-1}
Result:	the notified chemical was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity (4)

Species/strain:	rat/albino
Number/sex of animals:	5/sex
Observation period:	14 days

Method of administration:	the notified chemical in an oleum arachidis vehicle (4 $mL.kg^{-1}$)was applied to the shaved skin of test animals using semi-occlusive wrap for 24 hours
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines (limit test) (8)
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

not determined - dusts of the chemical not generated

9.1.4 Skin Irritation (5)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	7 days
Method of administration:	the notified chemical was moistened with 0.5% (w/v) carboxymethylcellulose (CMC) in 0.1% (w/v) aqueous polysorbate 80 and applied to the skin of test animals using semi-occlusive wrap for a period of 4 hours

Draize scores (9):

Time after treatment (hours)	***Animal #***				
	1	***24***	***48***	***72***	***168***
Erythema					
1	1[a]	1	0	0	0
2	1	1	0	0	0
3	1	1	1	1	0

[a] see Attachment 1 for Draize scales

Test method:	similar to OECD guidelines (8)
Comments	no oedema were recorded; very slight erythema detected
Result:	the notified chemical was slightly irritating to the skin of rabbits

9.1.5 Eye Irritation (6)

Species/strain:	rabbit/New Zealand white
Number/sex of animals:	3 females
Observation period:	3 days
Method of administration:	0.1 mL (~0.52 g) of the notified chemical was placed in the conjunctival sac of each animal; the untreated eye serving as a control
Comments:	no iridal or corneal effects noted over the entire test; conjunctival effects restricted to slight reddening of the conjunctiva, with these effects disappearing by the end of the observation period
Test method:	similar to OECD guidelines (8)
Result:	the notified chemical was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (7)

Species/strain:	guinea pig/Pirbright White
Number of animals:	20 test group; 10 control group
Induction procedure:	day 0 - three pairs of 0.1 mL intradermal injections were made on the left and right side of the shaved neck in the test and control animals. • adjuvant/physiological saline mixture 1:1 (v/v) • 5% notified chemical in oleum arachidis • 5% notified chemical in adjuvant/physiological saline mixture;

control groups treated similarly except notified chemical was absent

day 8 - epidermal challenge; 50% (w/w) of the notified chemical in vaseline applied to the neck of each animal using occlusive dressing for 48 hours

Challenge procedure: day 21 - test animals were treated with 30% (w/w) mixture of the notified chemical in vaseline; occlusive dressing for 48 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
30%	3/20**	8/20	0/20	0/20

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

Test method: similar to OECD guidelines (8))

Result: the notified chemical was moderately sensitising to the skin of guinea pigs

9.2 Repeated Dose Toxicity (10) (summary report only)

Species/strain: rat/albino

Number/sex of animals: 60/sex

Method of administration: the notified chemical in distilled water containing 0.5% CMC and 0.1% Tween was given to test animals by gavage once each day

Dose/Study duration:: 5 dose groups were used
0 $mg.kg^{-1}$
10 $mg.kg^{-1}$
50 $mg.kg^{-1}$
200 $mg.kg^{-1}$
1 000 $mg.kg^{-1}$
animals dosed once each day for 90 days

Clinical observations:	none
Clinical chemistry/Haematology:	increase in the activity of alanine aminotransferase and aspartate aminotransferase in all animals of the 1 000 $mg.kg^{-1}$ group; females in the 200 $mg.kg^{-1}$ showed the same effect; these effects were not reversible in the male group and only partially reversible in the female groups
Histopathology:	*microscopic:* treatment-related effects were present in animals of the 200 and 1 000 $mg.kg^{-1}$ groups; necrosis of liver hepatocytes and granuloma formation in the liver of the females of the 200$mg.kg^{-1}$ test group, and both male and females in the 1 000 $mg.kg^{-1}$ group; phagocytes in the mesenteric lymph node in males and females in the aforementioned groups; lesions of the liver and the lymph were not reversible within a 4-week recovery period; tubular lesion and hyaline change in the kidney of both 200 $mg.kg^{-1}$ and 1 000 $mg.kg^{-1}$ male test groups as well as myopathy of skeletal muscle in males of the 1 000 $mg.kg^{-1}$ group; these lesions were however reversible in a 4-week recovery period
Test method:	similar to OECD guidelines (8)
Result:	the liver, mesenteric lymph node and kidney of rats were the main target organs in a 3 month repeat dose study

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assays (11)

Strains:	TA 98, TA 100, TA 1535, and TA 1537; WP2 uvrA
Concentration range:	312.5 - 5 000 $\mu g.plate^{-1}$ of the notified chemical in an acetone suspension with or without S9 metabolic activation

Test method:	similar to OECD guidelines (8)
Result:	the notified chemical was not mutagenic in the bacterial strains tested with or without S9 metabolic activation

9.3.2 *In Vitro* Mammalian Cytogenic Assay (12)

Cell type:	L5178y mouse lymphoma cells
Concentration range	10 - 333 $\mu g.mL^{-1}$ of the notified chemical in DMSO vehicle with or without metabolic activation
Exposure period:	3 hours with metabolic activation; 24 hours without metabolic activation
Test method:	similar to OECD guidelines (8)
Result:	the notified chemical is not mutagenic in mouse lymphoma cells with or without S9 metabolic activation

9.3.3 Chromosomal Aberration Assay with Chinese Hamster Lung (CHL) Cells (13)

Cell type:	Chinese hamster lung cells
Concentration range	experiment 1 - 10, 33, 100 and 333 $\mu g.mL^{-1}$ of the notified chemical in DMSO vehicle with or without S9 metabolic activation (24 hour and 48 hour fixation time) experiment 2 - 33, 100 and 333 $\mu g.mL^{-1}$ of the notified chemical in DMSO vehicle with or without S9 metabolic activation (24 hour fixation time)
Exposure period:	3 hours with S9 metabolic activation; 24 hours without S9 metabolic activation
Test method:	similar to OECD guidelines (8)
Result:	the notified chemical is not clastogenic in Chinese hamster lung cells with or without S9 metabolic activation

9.4 Overall Assessment of Toxicological Data

The notified chemical was of low oral and dermal toxicity in the rat with both LD_{50} values exceeding 2 000 $mg.kg^{-1}$. When the notified chemical was applied to the skin of rabbits, slight eschar/erythema were produced, but no oedema. These effects had disappeared by the end of the observation period. Likewise, application of the notified chemical to the eyes of rabbits produced reversible effects in the conjunctiva of the animals. No iridal or corneal effects were noted.

The notified chemical was found to be a moderate skin sensitiser to the skin of guinea pigs in an adjuvant-type test, with 40% of the test animals scoring a positive response during challenge.

Repeat-dose studies in the rat showed that the liver and the mesenteric lymph nodes and kidney were target organs. The liver suffered necrosis of hepatocytes and granuloma formation, while the kidney developed tubular lesions. The no observed adverse effect level (NOAEL) is considered to be 50 $mg.kg^{-1}.day^{-1}$.

The notified chemical found not to be mutagenic in bacterial or mammalian cells. The notified chemical was also found to be non-clastogenic in an *in vitro* chromosomal aberration assay using Chinese hamster lung cells.

Based on the skin sensitising properties of the notified chemical, it would be classified as hazardous according to the National Occupational Health and Safety Commission's *Approved Criteria for Classifying Hazardous Substances.*

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been 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
Zebra Fish *(Brachydanio rerio)*	96 h acute	0, filtrate[b], 100	LC_{50} > 100 NOEC = 100	(14)
Water Flea (*Daphnia magna*)	48 h acute	0, filtrate[b], 100	EC_{50} > 100 NOEC = 100	(15)
Algae (*Selenastrum capricornutum*)	96 h growth	0, filtrate[b], 100	E_RC_{50} > 100 E_BC_{50} > 100 NOEC = 100	(16)
Sewage microorganisms	3 h respiration	0, 100	LC_{50} > 100 NOEC = 100	(17)

* NOEC - no observable effect concentration; [a] Nominal concentration. [b] Filtrate from 100 $mg.L^{-1}$ nominal concentration.

The ecotoxicity studies for the notified chemical were conducted at two concentrations, a nominal concentration of 100 $mg.L^{-1}$ (a precipitate of the test material was observed in all samples in the fish, daphnia and algal studies) and filtrates from solutions prepared at 100 $mg.L^{-1}$ nominal concentration. The maximum level of the chemical measured in these studies was 3.0 $mg.L^{-1}$ during the fish study and precipitate was noted to form in these samples with time. The maximum level measured in the daphnia study was 0.6 $mg.L^{-1}$ and the substance was not detected in the filtered solutions in the algal study.

In the range finding test for the daphnia study Tween 80 was used as a dispersant. The presence of Tween 80 appeared to increase the effect of the notified chemical on the test organisms, with 50 and 100% immobilisation observed after 48 hours for the filtrate and 100 $mg.L^{-1}$ samples. This contrasts with the final study that was conducted without the use of the additive, where no immobilised daphnia were observed.

No mortalities or unusual observations were made during the fish and algal studies. The notified substance showed no toxicity toward sewage microorganisms at a nominal concentration of 100 $mg.L^{-1}$.

The ecotoxicity data for the notified chemical indicate that it is not toxic to fish, algae or microorganisms at concentrations up to the limit of its solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be used as a stabiliser for polyolefin plastics. Losses during manufacture are expected to be low. Once incorporated into these products the notified chemical is expected to remain within the product matrices. Hence, the majority of the notified chemical will share the fate of the articles into which it is incorporated. It is anticipated that these will be disposed of to landfill or incinerated at the end of their useful lifetime. Incineration would destroy the chemical, and create typical decomposition products of water and oxides of carbon and nitrogen. In landfill it is expected that the notified substance will remain immobile within the matrices.

Waste from empty containers (total less than 8 kg per annum) will be disposed of to landfill where it is expected that it will be immobile.

Hence, the overall environmental hazard of the substance can be rated as low, given the low environmental exposure of the unbound chemical.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

According to the toxicological studies the most significant hazard associated with the notified chemical is its potential to cause skin sensitisation. However, the notified chemical may also cause slight eye and skin irritation in exposed

individuals.

The risk of adverse health effects in workers is in general likely to be low on account of the dust-free granulated form of the notified chemical, its low vapour pressure, and the engineering controls employed in the industries using the notified chemical.

Worker exposure and risk during handling and transport of the notified chemical is negligible given the packaging in sturdy polythene-lined fibre drums.

The notifier has indicated that the batching operations of customers is facilitated with engineering controls to minimise eye, skin and respiratory system exposure, hence the risk of adverse health effects in this phase of operations is expected to be minimal.

The notifier has also indicated that the blending operation, where the notified chemical and other additives are mixed with polymer powder/granules, is performed under local exhaust or through a closed system of transfer. Therefore, exposure and the risk of adverse health effects are likely to be negligible for blending operators.

Finally, the workers exposed to cooled polymer fibres have negligible risk of developing adverse health effects from the notified chemical, since it is encapsulated in the polymer matrix and unlikely to be leached.

There is negligible risk of the public suffering adverse health effects from contact with polymer fibres containing the notified chemical. As indicated, encapsulation of the notified chemical in the polymer matrix precludes public exposure.

13. RECOMMENDATIONS

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

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (18) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (19);
- Industrial clothing should conform to the specifications detailed in AS 2919 (20);
- Impermeable gloves or mittens should conform to AS 2161 (21);
- All occupational footwear should conform to AS/NZS 2210 (22);
- 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 (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* (23).

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

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15. Bogers M 1996, *96-Hour Acute Toxicity Study in Daphnia Magna with CGA 042*, Project no., 166837, NOTOX B. V., Hertogenbosch, Netherlands.

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18. Standards Australia 1994, *Australian Standard 1336-1994, Eye protection in the Industrial Environment*, Standards Association of Australia, Sydney.

19. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

20. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australia, Sydney.

21. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves)*, Standards Association of Australia, Sydney.

22. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

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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