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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Lutensol XL 80

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Director
Chemicals Notification and Assessment

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Lutensol XL 80

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN 62 008 437 867) of 500 Princes Highway Noble Park VIC 3174.

NOTIFICATION CATEGORY
Standard: Polymer with NAMW < 1000 (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Polymer Constituents, Purity, Hazardous and Non-hazardous Impurities/Residual Monomers, Additives/Adjuvants.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Part B: Vapour Pressure, Water Solubility, Hydrolysis as Function of pH, Partition Coefficient, Dissociation Constant, Flammability Limits, Explosive Properties, Reactivity.
Part C: Acute Dermal and Inhalation Toxicity, Skin Sensitisation, In Vitro/In Vivo Genotoxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
China (May 2003), Korea (October 2003), Canada and USA (under assessment).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Lutensol XL 80
Lutensol ES 94013
Eusapon LD 6030
Eusapon LD 6031
Eusapon OD

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None are present at above the relevant cut off level for classification of the notified polymer as a hazardous substance

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Import, pure substance

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100-200	100-200	100-200	100-200	100-200

USE
A non-ionic surfactant used at <4% for industrial detergents and cleaners.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
BASF Australia Ltd

TRANSPORTATION AND PACKAGING
Lutensol XL 80 (100% notified polymer) will be shipped and transported by road in 200 kg drums or 950 kg tanks from the wharf to the notifier's warehouse at North Laverton VIC for storage, and then to a number of customer blending facilities. The finished industrial cleaning products will be packed into 5 L and 20 L customer containers, and road transported to end users. Storage will be in a covered bunded area and in accordance with state legislation.

5.2. Operation description

The notified polymer will be brought into Australia as an essentially raw material with approximately 10 shipments per year.

At a customer blending facility, store persons will receive and transfer drums of the notified polymer by forklift to various work areas as required, for example, warehouse or batch formulating area. Various techniques are employed in delivering the correct quantities of the notified polymer and other ingredients according to the batch sheet. Most often this process involves placing the drum on a scale, inserting a dip pipe into the drum and pumping the desired quantity into blending vessels. These are enclosed tanks with a manway opening in well ventilated areas, while the transfer hose and dip pipe are then washed to effluent. At the end of the blend, laboratory technicians will perform testing and adjustment to the formulation specifications if necessary. The final product mixtures containing <4% notified polymer will be packed in a manual operation directly from the blender into customer containers via a hose and shut-off valve at the filling head. Pallets of packed product will then be stored and for sale to customers.

End use customers including janitorial cleaning staff and kitchen hands will wipe these cleaners and detergents over hard surfaces during industrial cleaning tasks which could take up to six hours a day.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage workers			
- import product	5	2 h	70 days/year
- formulated product	5	1 h	48 days/year
Store persons	5	0.5 h	24 days/year
Weighing and charging workers	10	1 h	24 days/year
Blending workers	10	0.5 h	24 days/year
Packing workers	5	2 h	24 days/year
QC laboratory technicians	2	0.5 h	24 days/year
End users (cleaning staff)	10000	2 - 6 h	240 days/year

Exposure Details
During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached. Should a spill occur, it is expected to be contained and collected using absorbent materials, and placed into suitable containers for recovery or disposal in accord with the MSDS and official regulations.

Laboratory technicians may be potentially exposed to the notified polymer when sampling and testing formulation samples containing it. However, they will handle only small quantities and will wear appropriate personal protective equipment.

Dermal and ocular exposure due to splashes and spillages can occur during weighing, mixing, packing, and equipment cleaning processes. For example, charging and blending workers when weighing and pumping the notified polymer from imported drums into a mixing tank and packing workers when connecting/disconnecting transfer hoses may be potentially exposed to the pure form of the notified polymer or at concentrations up to 10% respectively. Exposure of equipment cleaning and maintenance workers are anticipated to be less frequent and in smaller quantities.

The notifier indicates that adequate ventilation will be in place to prevent workers from breathing mist and volatiles. Operators of the formulation plants will wear splash proof goggles, chemically resistant gloves, boots, aprons, or other protective clothing, and appropriate respirators when required. In addition, current work procedures and practices for the use of a similar existing product are in place and directly applicable to the intended use of the notified polymer. Copies of the MSDS will be readily accessible in all work areas.

Exposure to the notified polymer during end use is expected to be widespread, frequent and extensive. This would include dermal contact with drips and spills and possibly accidental ocular contact when industrial cleaning workers apply and wipe over hard surfaces with cleaners and detergents containing the notified polymer. It is expected that the workers will wear suitable protective clothing and gloves when carrying out these activities.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported in Australia as a raw material. At a customer blending facility, if incidental spillage or wastes occur during normal operating procedures, it will be contained and soaked up with absorbent material before being transported off-site to an approved industrial facility for disposal by incineration or landfill. The transferring/pumping of the notified polymer into blending vessels and the packaging of the mixture into the final consumer products will be automated. The transfer hose and dip pipe are then washed to effluent. It is expected that <0.5% of the notified polymer would be discharged to effluent through the washout procedures. It is estimated that the maximum residue in the empty import containers will amount to 0.5%, corresponding to 1 tonne of the notified polymer per annum based on a maximum import of 200 tonnes. The residues will be discharged to effluent via drum recyclers.

RELEASE OF CHEMICAL FROM USE
The notified polymer will be used in detergents or cleaner products for industrial purposes only (eg floor cleaners) and it is unlikely to be sold to the public. While limited details are available, the notifier accepts practically all of the notified polymer will be discharged into sewer. Therefore, release is expected to be widespread and include both metropolitan and country areas. Small amount may remain in empty product containers, and be disposed of to landfill.

5.5. Disposal
The notifier recommends that liquid wastes of the notified polymer should be disposed of in a secure landfill.

5.6. Public exposure
The notified polymer is intended for use in industrial cleaning only. There is potential for dermal exposure among public members to hard surfaces that have been cleaned with products containing the notified polymer. However, exposure would be low because contact is only intermittent and with residues of the notified polymer.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Colourless to yellowish liquid with characteristic odour

Melting Point 10ºC

Remarks Full test report was not provided.

Density 1000 kg/m^3 at 20ºC

Remarks Full test report was not provided.

Vapour Pressure Not determined

Remarks Vapour pressure of the notified polymer is expected to be low based on its high molecular weight.

Water Solubility Not determined

Remarks From a stability test discussed below, Eusapon LD 6026, an analogue of the notified polymer, was completely dissolved at 2 g/L. Considering that the notified polymer contains more hydrophobic constituents, its water solubility is expected to be less than those of this analogue.

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer has no functional groups that are likely to hydrolyse within the environmental pH range of 4-9. Results of a stability test on its analogue would support this conclusion (see below).

Partition Coefficient (n-octanol/water) Not determined

Remarks The notifier indicates that the logPow determination cannot be applied to surfactants as these surface active substances will be enriched in the phase boundary. Based on its relatively high water solubility, it is likely that the notified polymer will partition mainly to the aqueous phase.

Adsorption/Desorption

METHOD ISO 18749:2001 Water quality – Adsorption of substances on activated sludge: Batch test using specific analytical methods.

Soil Type	*Dissolved Organic Carbon – DOC Nominal Concentration (mg/L)*	*Time (h)*	*Mean DOC Elimination (%)*
Activated sludge	50	0	0
	50	3	4
	50	24	13

Remarks Test was conducted on Lutensol ON 110 (details of this analogue are claimed exempt from publication) in triplicate using a mixture of an inorganic medium, activated sludge and the test substance that simulates conditions of wastewater treatment plants. The measured DOC concentrations at 0, 3, and 24 h of the test substance are used as the basis for calculating the degree of adsorption.
It was noted that the use of DOC generally requires relatively high test concentrations (usually not less than 40 mg/L) and it is not a specific method (ie no direct differentiation between adsorption and/or elimination mechanisms such as complex formation, flocculation, precipitation, sedimentation or biodegradation). There may be, however, cases where no acceptable alternative is

available as for water soluble or miscible polymers and such a test concentration is usually too high compared with concentrations found under real wastewater conditions.
The analogue chemical is not likely to be strongly adsorbed. However, the adsorption of the notified polymer would be higher due to its greater hydrophobicity.

TEST FACILITY BASF Aktiengesellschaft (2002a)

Dissociation Constant Not determined

Remarks The notified polymer has no functional groups that are likely to dissociate under the environmental pH 4-9.

Particle Size Not applicable

Remarks The notified polymer is a liquid at room temperature.

Flash Point >100°C

METHOD DIN 51798 (Pensky-Martens closed cup)
Remarks Full test report was not provided.

Flammability Limits Not determined

Remarks The notified polymer is not expected to be flammable.

Autoignition Temperature >200°C

METHOD DIN 51794
Remarks Full test report was not provided.

Explosive Properties Not determined

Remarks The notified polymer is not expected to be explosive on structural ground.

Reactivity Stable under normal environmental conditions

Remarks Results of a stability test submitted (BASF GKA Analytik 2002) would support this conclusion. The test showed Eusapon LD 6026 (details of this analogue are claimed exempt from publication) dissolved at 2 g/L was stable in buffer pH 1.2, 4, 7, and 9 for up to 14 days under 40°C and natural sunlight. Analysis methods were Total Organic Carbon and Gel Permeation Chromatography. The notified polymer is also not expected to degrade, decompose or undergo hazardous polymerisation. However, it may not be compatible with reactive chemicals and extremes of temperature.

7. TOXICOLOGICAL INVESTIGATIONS

No toxicity data were available for the notified polymer. However, the notifier submitted the following toxicity information in relation to structural analogues, which are representative of certain parts of the notified polymer. They are denoted as analogue A (which is also marketed as Lutensol XL 800 or Eusapon LD 6026), analogue B, and analogue C (a non-ionic surfactant category of alcohol/alkylphenol ethoxylates, Talmage 1994). Details of analogues A and B are claimed exempt from publication.

Analogue A is considered to be most chemically similar to the notified polymer and best represent the effects of acute exposure. Analogue C is also most relevant for acute exposure. Analogue B is the major expected metabolite of the notified polymer and is therefore relevant for subchronic effects.

The toxicological endpoints submitted for analogues A & B are presented below:

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >200 to <2000 mg/kg bw	harmful (analogue A)
Rat, acute dermal	test not conducted
Rat, acute inhalation	test not conducted
Rabbit, skin irritation	slightly irritating (analogue A)
Rabbit, eye irritation	severely irritating (analogue A)
Guinea pig, skin sensitisation	test not conducted
Rat, oral repeat dose toxicity - 90 days	NOAEL = 150 (male) and 30 (female) mg/kg bw/day (analogue B)
Genotoxicity – bacterial reverse mutation	non mutagenic (analogue B)
Genotoxicity – in vitro	test not conducted
Genotoxicity – in vivo	test not conducted
Pharmacokinetic/Toxicokinetic studies	no data available
Developmental and reproductive effects	NOAEL = 158 mg/kg bw/day (analogue B)
Carcinogenicity	no data available

7.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue A
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 96/54/EC B.1tris Acute Oral Toxicity – Acute Toxic Class Method. US EPA OPPTS 870.1100 Acute Oral Toxicity.
Species/Strain	Rat/Wistar CrlGlxBrlHan:WI
Vehicle	Doubly distilled water
Remarks – Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 males	200	0/3
II	3 females	200	0/3
III	3 females	2000	2/3

LD50	>200 to <2000 mg/kg bw
Signs of Toxicity	The 2000 mg/kg females showed poor general state, dyspnoea, apathy, ataxia, staggering, abdominal and lateral position, salivation and piloerection from administration to Day 1. No clinical sings and findings were observed in the 200 mg/kg females while one male of this dose group showed impaired general state, gasping and respiratory sounds on Day 1. The mean body weights of the 200 mg/kg dose group increased throughout the 14 day study period.
Effects in Organs	No macroscopic pathologic abnormalities were noted in any animals, either at study termination or in the two animals that died 2 hour and 1 day after administration.
Remarks – Results	The isolated findings in one male of the 200 mg/kg dose group were considered to be associated with the gavage procedure.
CONCLUSION	The analogue chemical is harmful via the oral route.
TEST FACILITY	BASF Aktiengesellschaft (2001a)

7.2. Acute toxicity – dermal

Remarks	Test was not conducted. Analogue C chemicals have been shown to

exhibit a low order of dermal toxicity (Talmage 1994).

7.3. Acute toxicity – inhalation

Remarks	Test was not conducted. Inhalation exposure would be unlikely due to the expected low vapour pressure of the notified polymer. Also, analogue C chemicals have been shown not to be acutely toxic to rats at concentrations less than or equal to their saturated vapour concentrations in air (Talmage 1994).

7.4. Irritation – skin

TEST SUBSTANCE	Analogue A
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation). US EPA OPPTS 870.2500 Acute Dermal Irritation.
Species/Strain	Rabbit/New Zealand White
Number of Animals	1 male, 2 females
Vehicle	None – applied undiluted as supplied
Observation Period	7 days
Type of Dressing	Semi-occlusive
Remarks – Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1.0	1.7	2.0	2	3 d	0
Oedema	0.0	0.0	0.0	0	0 d	0

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

Remarks – Results	Slight to moderate erythema (grade 1-2) with scaling or severe scaling was seen in all animals. The reactions resolved within 7 days after treatment except scaling was still observed in one animal at study termination. No oedema was noted. Primary irritation index = 1.6 (slightly irritating).
CONCLUSION	The analogue chemical is slightly irritating to the skin.
TEST FACILITY	BASF Aktiengesellschaft (2001b)

7.5. Irritation – eye

TEST SUBSTANCE	Analogue A
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation). US EPA OPPTS 870.2400 Acute Eye Irritation.
Species/Strain	Rabbit/New Zealand White
Number of Animals	1 male
Observation Period	14 days
Remarks – Method	Due to the severe irritation findings, the study was terminated on day 14 and additional animals were not tested.

RESULTS

Lesion	*Mean Score* Animal No.*	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1			
Conjunctiva: redness	3.0	3.0	14 d	2.0
Conjunctiva: chemosis	2.3	3.0	14 d	2.0
Conjunctiva: discharge	1.7	3.0	14 d	1.0
Corneal opacity	1.0	4.0	14 d	4.0
Iridial inflammation	1.0	1.0	72 h	0.0

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

Remarks - Results: Moderate to severe ocular reactions were observed, including eyelid retraction, suppuration, contracted pupil, cornea vascularisation and blood discharge. Iritis was reversible by day 7, but corneal opacity and vascularisation had progressively increased covering up to 2/3 of the corneal area. These reactions were considered irreversible and hence the study was terminated on day 14.

CONCLUSION: The analogue chemical is severely irritating to the eye.

TEST FACILITY: BASF Aktiengesellschaft (2001c)

7.6. Skin sensitisation

Remarks: Test was not conducted. Analogue C chemicals have not been shown to be skin sensitisers (Talmage 1994).

7.7. Repeat dose toxicity

TEST SUBSTANCE: Analogue B

METHOD: OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
EC Directive 88/302/EEC B.26 Sub-Chronic Oral Toxicity Test: 90-Day Repeated Oral Dose Study using Rodent Species.

Species/Strain: Rat/Fischer F-344
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 90 days
Dose regimen: 7 days per week
Post-exposure observation period: 0 day
Vehicle: 0.005% Cremophor EL (castor oil, ethoxylated) in doubly distilled water
Remarks - Method: Control was used for both vehicle and doubly distilled water.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
0 (control – water)	10 per sex	0	0/20
I (control – vehicle)	10 per sex	0	0/20
II (low dose)	10 per sex	30	0/20
III (mid dose)	10 per sex	150	0/20
IV (high dose)	10 per sex	600	0/20

Mortality and Time to Death
All animals survived until the scheduled study termination.

Clinical Observations

As a reversible effect of treatment, salivation and/or urine-smeared anogenital region were seen in high dose animals within 3-4 h after administration. They were assessed as local rather than systemic effects. Other high dose treatment related effects were impairment of food consumption in males and females (18% and 10% vs controls respectively) and impairment of body weight/body weight change (14%/25% vs vehicle controls) in males throughout the observation periods. Mean terminal body weight was also significantly decreased in high dose males and females (17% and 8% vs vehicle controls respectively). No statistically significant deviations were observed in the other dose groups. There were no other abnormal clinical or ophthalmological observations.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

The most prominent finding in clinical pathology was the increase in cyanide-insensitive palmitoyl-CoA-oxidation in the high dose animals. This is probably caused by hepatic peroxisome proliferation which is accompanied by induction of peroxisomal enzymes particularly those involved in β–oxidation of fatty acids. As a result of the increased fatty acid metabolism, cholesterol concentrations in the sera of the high dose males and females and triglyceride level in the high dose males were significantly reduced. However, the slight increased triglyceride level in the high dose females was difficult to interpret, and thus was assessed as being incidental in nature. Moreover, the statistically significant decreased cholesterol (as well as the increased albumin) in the mid dose males compared with water control was also considered to be fortuitous, because this finding is marginal and was not evident when compared with vehicle control.

The decrease in platelet counts and globulins and the increase in albumin in the high dose animals of either sex were regarded to be treatment related. They are indicative of disturbance of protein metabolism. However the mechanism of the fall in platelets is unclear because there are no concomitant changes in clinical examinations and pathology which might explain the cause of this isolated finding.

Changes in urinalyses (such as increased squamous epithelial cells in high dose males, increased transitional and squamous epithelial cells and increased urinary volume with decreased specific gravity in high dose females) were regarded as signs of a mild nephrotoxic potential of the test substance at a dose level of 600 mg/kg.

Effects in Organs

The mean absolute and relative liver weights were significantly increased in high dose male and female rats (28%/54% and 25%/36% vs vehicle controls respectively). The relative liver weight was also significantly increased in mid dose females (6%), revealing a dose response relationship. Other changes in absolute and/or relative organ weights (adrenal glands, kidneys, ovaries, testes, epididymides, and brain) were also seen in high dose animals.

The liver weight increase was related to liver cell hypertrophy most likely due to peroxisome proliferation. In high dose male rats, there was also loss of fatty infiltration of the liver cells. However, this alteration of the endogenous lipid metabolism would not represent a pathological situation but rather an adaptation, probably attributed to the significantly decreased mean terminal body weight seen in this group.

In the high dose male group, the thyroid follicular epithelium was hypertrophic (7/10 animals) and in three of them, thyrotropic basophilic cells in the glandular part of the pituitary gland were enlarged, vacuolated, and intensively pink. This may be related to an accelerated metabolic degradation of T3 and/or T4 in the liver, resulting in a negative feedback over the hypothalamic pituitary axis.

Remarks – Results

Statistically significantly decreased values (vs vehicle controls) obtained for body weight/body weight change in high dose females were assessed as being incidental and hence not treatment related because of the fact that the body weight of the vehicle control was slightly higher than that of the water control. Consequently, due to the significantly decreased mean terminal body weight (vs vehicle controls), changes seen in mean absolute and/or relative weights of brain, kidney, adrenal glands, epididymides, testes or ovaries in high dose animals were regarded as by chance deviations. Impairment of food efficiency in the high and mid dose males and females was also assessed as being incidental because they were isolated significances with no dose response relationship. Gross lesions or microscopic findings in spleen, stomach, trachea, etc. were also interpreted to have arisen fortuitously since they were individual observations and by no means related to treatment.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 150 and 30 mg/kg bw/day in male and female rats respectively in this study, based on effects on the liver.

TEST FACILITY BASF Aktiengesellschaft (1996)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Analogue B

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 92/69/EEC B.14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure/Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	With and without metabolic activation: Test 1: 20, 100, 500, 2500, 5000 µg/plate Test 2 & 3: 15, 30, 60, 120, 250 µg/plate
Vehicle	DMSO
Remarks – Method	Three independent tests (2x plate incorporation and 1x pre-incubation) were conducted in triplicate.

RESULTS

Metabolic Activation	*Cytotoxicity in Preliminary Test*	*Test Substance Concentration (µg/plate) Resulting in: Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	Not conducted	≥500	>5000	Negative
Test 2	--	≥250 (TA1535 only)	>5000	Negative
Test 3	--	≥120	>5000	Negative
Present				
Test 1	Not conducted	≥500	>5000	Negative
Test 2	--	≥250 (TA1535 only)	>5000	Negative
Test 3	--	≥120 (all) & ≥250 (TA1537 only)	>5000	Negative

Remarks – Results No increases in the his^+ revertant numbers were observed both in the plate incorporation and pre-incubation tests with any tester strains at any concentrations in either with or without S9 mix. A bacteriotoxic effect (reduced his^- background growth and/or his^+ revertant numbers) was observed at ≥120 – 250 µg/plate depending on the strains and test conditions. The vehicle and positive controls responded appropriately.

CONCLUSION The analogue chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY BASF Aktiengesellschaft (1995a)

7.9. Genotoxicity – in vitro

Remarks Test was not conducted. Analogue C chemicals have been shown negative in a variety of short-term genotoxicity tests (Talmage 1994).

7.10. Genotoxicity – in vivo

Remarks Test was not conducted. Chromosome damage was not observed in

dominant lethal and bone marrow cytogenic tests when an analogue C chemical was administered orally to rats and hamsters (Talmage 1994).

7.11. Developmental toxicity

TEST SUBSTANCE	Analogue B
METHOD	OECD TG 414 Teratogenicity. EC Directive 88/302/EEC B.31 Teratogenicity – Rodent and Non-rodent. US EPA 40 CFR 798.4900 Developmental Toxicity Study.
Species/Strain	Rat/Wistar Chbb:THOM (SPF)
Route of Administration	Oral – gavage
Exposure Information	Exposure days: 6 – 15 post coitum Post-exposure observation period: 5 days
Vehicle	0.005% Cremophor EL (castor oil, ethoxylated) in doubly distilled water
Remarks – Method	Control was used for both vehicle and doubly distilled water.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
0 (control – water)	10 females	0	0/10
I (control – vehicle)	10 females	0	0/10
II (low dose)	10 females	158	0/10
III (mid dose)	10* females	790	0/10
IV (high dose)	10 females	1580	9/10

* two were excluded from evaluation as not being pregnant.

Mortality and Time to Death

9/10 high dose females died intercurrently between days 8-11. Other animals survived until the scheduled sacrifice on day 20.

Effects on Dams

Numerous adverse clinical findings like apathy, unsteady gait, chromodacryorrhea, poor general/nutritional state, salivation and urine smeared fur were observed in high dose animals before and/or after the daily intubation. Furthermore, the only surviving high dose dam, which resorbed all of its implants during late gestation, showed vaginal haemorrhage on days 12, 13 and 15. In mid dose animals, salivation was seen after the daily treatment between days 8-15.

Food consumption and hence body weight/body weight gain were statistically significantly reduced in mid and high dose females, primarily during the exposure period (days 6-15). The impairments were also shown statistically significant on the first day post exposure for food consumption and from days 8-20 for body weight in the only surviving high dose dam, when compared to controls.

Due to the resorption of all implants, uterus weight of this high dose dam was drastically reduced, while the significantly reduced mean uterus weight of the mid dose dams was caused by clear reductions in the foetal body weights in this group. Relative liver and kidney weights were statistically significantly increased (61% and 45% respectively) in the surviving high dose animal. A slight, but statistically significantly increase in relative liver weights (8%) occurred also in the mid dose animals. These findings were regarded to be treatment related.

At necropsy, stomach ulcerations and/or erosions were found in 4/10 high dose rats that died intercurrently. The surviving high dose rat showed a papillomatous hyperplasia in the forestomach, probably attributed to the irritation properties of the test substance.

All implants of this dam were resorbed, thus the post-implantation loss was 100%. Only small amounts of foetal tissue in addition to placental tissue were visible, which contrast to the usual appearance of the uterine mucosa in case of late resorptions.

The conception rate reached 100% in all control and test groups except the mid dose group which reached 80%.

Effects on Foetus
Due to the premature death of all implants, no foetuses could be evaluated in the high dose group.

In the mid dose group, the mean foetal body weight was statistically significantly lower (10%) than the two control groups, and this was considered to be treatment related. In addition, the rate of skeletal malformations (36%) was distinctly increased as were the incidences of skeletal variations and retardations (68% and 98% affected foetuses/litter respectively). The increased skeletal malformations and variations were predominantly due to the occurrence of asymmetrical dumbbell-shaped thoracic vertebral bodies and of irregular-shaped sternebrae and accessory 14th ribs respectively. The increased rate of retardations in the skeletal maturation was in line with the lower mean foetal body weight, particularly substantiated by incompletely ossified skull bones and incompletely ossified or dumbbell-shaped (symmetrical) thoracic vertebral bodies in this test group. Thus, 790 mg/kg bw/day caused clear teratogenic effects and other signs of developmental toxicity.

Remarks – Results
There were no statistically significant and/or biological relevant differences between any dams/foetuses of the control and low dose test groups. Soft tissue malformations (dextrocardia) and variations (dilated renal pelvis and/or hydroureter) were assessed to be spontaneous in nature and hence not treatment related due to lack of a clear dose response relationship.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 158 mg/kg bw/day in maternal and foetal subjects in this study, based on teratogenic effects.

TEST FACILITY BASF Aktiengesellschaft (1995b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

8.1.1.1. Study 1

TEST SUBSTANCE Notified polymer

METHOD ISO 9439:1999 Water quality – Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium: CO2 Evolution, equivalent to OECD TG 301 B Ready Biodegradability: CO2 Evolution (Modified Sturm).

Inoculum	Activated sludge from laboratory wastewater plants treating municipal sewage
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2 and DOC
Remarks - Method	Test was conducted in duplicate at a nominal concentration of 32 mg/L (equivalent to 20 mg/L TOC). % degradation = $CO_2/ThCO_2$, where $ThCO_2$ = theoretical CO_2 production calculated from elemental analysis. The combination of both CO_2 and DOC measurements allows a prediction of biodegradability and abiotic removal of the test substance, eg by adsorption onto sludge.

RESULTS

Test Substance			*Reference Substance – Aniline*		
Day	*% Degradation*	*% DOC Elimination*	*Day*	*% Degradation*	*% DOC Elimination*
1	0	19	1	0	0
5	3	55	5	28	92

10	20	54	10	52	89
14	33	60	14	68	90
21	47	62	21	83	90
28	63	74	28	101	100

Remarks - Results: The degradation of the notified polymer was >60% within 28 days. It did not meet the OECD 10-day window criteria (60% degradation within 10 days of reaching 10%). However, as a surfactant the notified polymer is possibly a multi-component substrate and typically characterised by different degradation steps. Thus the 10-day window criteria do not apply (CSTEE 1999 and in line with Regulation (EC) No. 648/2004), and it is considered readily biodegradable. The degradation of the reference substance and the inhibition control were >60% and >25% after 14 days respectively, confirming the validity of the test and that the notified polymer is not inhibitory to sewage microorganisms.

CONCLUSION: The notified polymer is considered readily biodegradable.

TEST FACILITY: BASF Aktiengesellschaft (2003a)

8.1.1.2. Study 2

TEST SUBSTANCE: Notified polymer

METHOD: ISO 9439:1999 Water quality – Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium: CO2 Evolution, equivalent to OECD TG 301 B Ready Biodegradability: CO2 Evolution (Modified Sturm).

Inoculum: Activated sludge from laboratory wastewater plants treating municipal sewage

Exposure Period: 28 days

Auxiliary Solvent: None

Analytical Monitoring: CO_2 and DOC

Remarks - Method: Test was conducted in duplicate at a nominal concentration of 33 mg/L (equivalent to 20 mg/L TOC). % degradation = $CO_2/ThCO_2$, where $ThCO_2$ = theoretical CO_2 production calculated from elemental analysis. The combination of both CO_2 and DOC measurements allows a prediction of biodegradability and abiotic removal of the test substance, eg by adsorption onto sludge.

RESULTS

Test Substance			*Reference Substance – Aniline*		
Day	*% Degradation*	*% DOC Elimination*	*Day*	*% Degradation*	*% DOC Elimination*
1	-1	1	1	-1	-2
5	3	16	5	23	106
10	28	64	10	48	101
14	49	67	14	62	95
21	59	76	21	77	101
28	72	77	28	89	96

Remarks - Results: The degradation of the notified polymer was >60% within 28 days. Therefore, it is considered readily biodegradable for the same reasons as above. The degradation of the reference substance and the inhibition control were >60% and >25% after 14 days respectively, confirming the validity of the test and that the notified polymer is not inhibitory to sewage microorganisms.

CONCLUSION: The notified polymer is considered readily biodegradable.

TEST FACILITY BASF Aktiengesellschaft (2002b)

8.1.2. Bioaccumulation

Remarks No bioaccumulation study was provided for the notified polymer. However, based on the expected solubility of the notified polymer and its relatively low NAMW of 600, there is a potential for bioaccumulation to occur.

8.2. Ecotoxicological investigations

8.2.1. Chronic toxicity to fish

TEST SUBSTANCE Notified polymer

METHOD OECD TG 210 Fish Early Life Stage Toxicity Test.
US EPA FIFRA 72-4(a) Fish Early Life Stage Toxicity Test.
US EPA OPPTS 850.1400 Fish Early Life Stage Toxicity Test.

Species *Pimephales promelas* (Fathead minnow)
Exposure Period 33 days
(31 days after the start of hatch – day 2, and 28 days after the majority of larvae had hatched – day 5)
Auxiliary Solvent None
Medium Drinking water (unchlorinated)
Water Hardness 98-101 mg $CaCO_3$/L
Analytical Monitoring TOC and LC/MS
Remarks – Method Test was conducted under flow through conditions in four replicates with fertilised eggs of <6 h old at the start of exposure that were laid by 8 different breeding groups of fathead minnows. Statistical evaluation were Dunnett's test [a simultaneous comparison of several dose groups with the control – two sided] for body weights (wet and dry) and lengths of the fish, and Fisher's test [a pairwise comparison of each dose group with the control – one sided] for the embryo, larvae and fish survival.
The temperature, pH, oxygen content, conductivity, acid capacity and total hardness were within acceptable limits over the exposure period.

RESULTS

Concentration (mg/L)		*Number of*	*Mean Survival Rates (%) for*			
Nominal	*Actual*	*Fertilised Eggs*	*Embryo (Day 0)*	*Larvae (Day 0-9)*	*Young Fish (Day 9-33)*	*Surviving Fish (Day 0 –33)*
0.0	0.00	100	90	93	96	81
0.1	0.06 (60%)	100	92	90	99	82
0.3	0.19 (64%)	100	91	90	95	78
1.0	0.98 (98%)	100	89	88	96	75
3.0	2.78 (93%)	100	83	86	89	63
10.0	9.90 (99%)	100	32	0	0	0

NOEC and LOEC NOEC = 0.98 mg/L and LOEC = 2.78 mg/L (measured concentrations) based on impairment of body weight/length or growth.

Remarks – Results Over the 33-day exposure period, survival was statistically significantly decreased in comparison to the control group in all concentrations ≥3.0 mg/L. Mortality occurred predominantly during or shortly after hatch.

A clear test substance related effect was the delayed time to hatch in the nominal concentration group of 10 mg/L (hatch started at day 3 of exposure and completed on day 7 vs 3-6 days in the control group). Body weight and length were statistically significantly reduced in the surviving

fishes exposed to nominal concentrations ≥3.0 mg/L. No abnormalities in appearance or behaviour were observed in any of the test groups surviving until sacrifice.

The two lower measured concentrations were below the nominal concentration on several occasions due to the unexpected rapid degradation of the test substance in the stock solution. Since these two concentrations were below NOEC, the deviation was not considered to affect the NOEC determination and therefore the validity of the results.

CONCLUSION The notified polymer is considered to be slightly toxic to fish (Mensink et al 1995).

TEST FACILITY BASF Aktiengesellschaft (2004)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Analogue A

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test – Static.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static.
US EPA OPPTS 850.1010 Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids.
ISO 6341:1998 Water quality – Determination of the inhibition of the mobility of *Daphnia magna* Straus (Cladocera, Crustacea) – Acute Toxicity Test.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Medium	M4 water (ultrapure, demineralised, synthetic fresh water according to ISO 10706), then aerated with oxygen until saturation
Water Hardness	220-330 mg $CaCO_3$/L
Analytical Monitoring	Potentiographic titration with a surfactant sensitive electrode
Remarks - Method	Test was conducted in four replicates. Statistical evaluation for EC50 was the moving average method. The temperature, pH, and oxygen content were within acceptable limits during the test.

RESULTS

Concentration (mg/L) Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
0	20	20	19
6.25	20	20	20
12.5	20	20	19
25	20	18	13
50	20	15	8
100	20	0	0

LC50	37.3 mg/L (95%CI: 29.8-46.6) at 48 hours
Remarks - Results	The test concentrations remained stable with recovery >80% and thus nominal concentrations were presented without transformation.

CONCLUSION The analogue chemical is considered to be harmful to daphnia.

TEST FACILITY BASF Aktiengesellschaft (2001d)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test. US EPA OPPTS 850.5400 Alga Toxicity Test.
Species	*Desmodesmus subspicatus* CHODAT SAG 86.81
Exposure Period	96 hours
Concentration Range	
Nominal	0.391, 0.781, 1.56, 3.13, 6.25, 12.5, 25, 50, 100 mg/L
Auxiliary Solvent	None
Medium	Deionised water
Water Hardness	Not reported
Analytical Monitoring	In vivo chlorophyll-a-fluorescence at 0, 24, 48, 72, and 96 h
Remarks - Method	Three replicates per each test concentration and five replicates for the control were used. The stability of the test substance was guaranteed by the sponsor and thus no concentration control analysis were performed. The pH and temperature remained within acceptable limits during the test.

RESULTS

Biomass		*Growth*	
Nominal E_bC50 mg/L at 96 h	*Nominal NOE_bC mg/L at 72 h*	*Nominal E_rC50 mg/L at 96 h*	*Nominal NOE_rC mg/L at 72 h*
23.2	6.25	40.2	6.25

Remarks - Results	The test appears to meet the validity criteria.
CONCLUSION	The notified polymer is considered to be harmful to alga.
TEST FACILITY	BASF Aktiengesellschaft (2003b)

8.2.4. Inhibition of microbial activity

Remarks	Test was not conducted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Potentially all of the notified polymer for industrial uses will be released into the sewer when used cleaning water is released. The notified polymer is considered to be relatively soluble in water and is considered readily biodegradable in the 28-day biodegradation test under the EU conditions for surfactants. Therefore it is likely to be biodgradable in water and is unlikely to be adsorbed fully in the activated sludge or the sediments.

In calculating the PEC, the following were assumed: (1) usage of the maximum import volume of 200 tonnes is evenly distributed over a 365 day period; (2) usage is nationwide, with a population of 20 million contributing 200 L of water per person per day to the sewer; (3) there is no adsorption or degradation in the sewer prior to release. Hence, the daily PEC in a worst-case scenario in the sewage effluent is estimated as [200 x 10^{12} µg/(200 L x 20x10^6 persons x 365 days)] = 140 µg/L.

Due to lack of partition coefficient values, the modelling using the SimpleTreat model (European Commission 2003) could not be performed for partitioning and losses of the notified polymer in sewage treatment plants (STP). The notifier indicates that the elimination degree in the biodegradation study is >70% and should be used for PEC calculation in release water.

However, it should be noted that the elimination degree is based on a 28 days exposure and the residence time in most sewage plants is <1 day. Hence, this will not be taken into account in the PEC calculation. Based on the adsorption data on activated sludge for the analogue Lutensol ON 110 as well as the biodegradability data after 1 day for the notified polymer, it is reasonable to assume that approximately 15% of the notified polymer will be absorbed in the sludge in a 24 h period. Therefore, the PEC in the sewage effluent is calculated to be 0.85 x 140 = 119 µg/L.

Based on the respective dilution factors of 1 and 10 for rural areas and coastal discharges of effluents, the PECs of the notified polymer in these watercourses may approximate 140 and 14 µg/L or 119 and 11.9 µg/L when mitigated, respectively.

9.1.2. Environment – effects assessment

The aquatic toxicity data are summarised as follows:

Algae: 96 h EC50 = 23.2 mg/L; 72 h NOEC = 6.25 mg/L
Daphnia magna: 48 h EC50 = 37.3 mg/L
Fathead minnow: 33 day (chronic) NOEC = 0.98 mg/L

The Predicted No Effect Concentration (PNEC) is 19.6 µg/L, using an Assessment Factor (AF) of 50 based on the availability of the ecotoxicity data for fish and alga, and the chronic NOEC for fish of 0.98 mg/L.

9.1.3. Environment – risk characterisation

The mitigated PECs and Risk Quotients (Q) for the aquatic environment are calculated below:

Sewage effluent	*PEC*	*Q*
Coastal city	11.9	11.9/19.6 = 0.61
Rural areas	119	119/19.6 = 6.1

The risk quotients indicate an acceptable risk (Q<1) for marine release but a potential risk for freshwater organisms. However, since it is not expected that all will be released to the sewer or fresh water and given the industrial use, most will be used in major cities and thus the risk is acceptable. Should import levels rise above 200 tonnes per annum the hazard needs to be revised. This will include a better estimate of the release to the sewer and a chronic daphnia test result should be provided to allow use of an AF of 10.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During transport and storage, workers are unlikely to be exposed to the notified polymer. In the event of an accident, spills will be removed in accord with the MSDS and government regulations.

During reformulation, blending, weighing or packing procedures, dermal and ocular exposure will potentially occur due to splashes, drips and spills of the notified polymer, particularly, when workers connect or disconnect transfer hoses, pump the notified polymer from bulk containers into a blend tank, or pack the final cleaning product into consumer containers. Workers may also make dermal contact with contaminated surfaces when inserting bungs and labelling the containers and residues of the notified polymer when flushing blend tanks and transfer lines to effluent. However, the blending and packaging processes are mainly semi-automated and will occur in an enclosed system, worker intervention is not required unless the machine malfunctions or needs adjustment. The plant operators generally receive adequate training in handling surfactants and detergents, observe safe work practices and wear personal protective equipment such as gloves, chemical goggles, protective clothing, and respirators when required.

During end use in industrial cleaning tasks exposure would be widespread, frequent and extensive. However, workers will wear gloves, overalls and safety boots.

Overall, on the basis of the engineering controls, industrial hygiene, safe work practices and personal protective equipment, occupational exposure to the notified polymer would be limited.

9.2.2. Public health – exposure assessment

The industrial cleaning products containing the notified polymer are not available for sale to the public. The potential for public exposure to the notified polymer via dermal contact with hard surfaces cleaned with these products is assessed as being sporadic and negligible.

9.2.3. Human health - effects assessment

Based on the available toxicity data of its analogues, the notified polymer is expected to be harmful if swallowed (LD50 per oral, rat: 200 < LD50 ≤ 2000 mg/kg). It would a skin irritant and may cause serious damage to eyes on exposure. As a non-ionic surfactant, the notified polymer would have low sensitising potential, however, long-term exposure can lead to a weakening of the skin barrier by helping the transport of molecules (KCPC 2004). The NOAEL was established as 150 (male) and 30 (female) mg/kg bw/day in a 28-day repeat dose oral study in rats, based on effects of the analogue B on the liver, particularly the increased liver weight and cyanide-insensitive palmitoyl-CoA-oxidation. In the developmental toxicity study of the same analogue submitted, the NOAEL was established as 158 mg/kg bw/day in maternal and foetal subjects, based on teratogenic effects. The notified polymer is expected to be negative in vitro and in vivo genotoxicity assays.

Based on the available data the notified polymer is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The notified polymer is a hazardous chemical based on the available toxicological data. However, the OHS risk presented by the notified polymer would be low, given the automated process and engineering controls implemented at customer blending facilities, the industrial hygiene, the good work practices and safety measures including use of appropriate personal protective equipment by workers. Moreover, the notified polymer will be used at formulation sites where operatives are familiar in using such products and good handling procedures and housekeeping are the norm.

Large numbers of industrial cleaning workers will be potentially exposed to the products containing the notified polymer. However, they are adequately trained and wear suitable protective clothing and gloves when carrying out these activities. While oral exposure is unlikely, workers are advised to avoid eye and skin contact with products containing it and observe general hygiene practices such as washing of hands thoroughly once completing their cleaning tasks. In addition, the concentration of the notified polymer in these end use cleaning products will not exceed 4%.

9.2.5. Public health – risk characterisation

Given the notified polymer will only be used in the cleaning industry, the risk to public health is considered negligible.

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

10.1. Hazard classification

Based on the available data the notified polymer is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

- R22 – Harmful if swallowed;
- R38 – Irritating to skin;
- R41 – Risk of serious damage to eyes

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

The notified polymer is classified as harmful if swallowed (category 4), irritant to skin (category 2), and serious damage to eyes (category 1) under the GHS.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

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 Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer and product containing it (Degrease-It) provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified polymer and product containing it (Degrease-It) provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified polymer:
  - R22 – Harmful if swallowed;
  - R38 – Irritating to skin;
  - R41 – Risk of serious damage to eyes

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - conc ≥ 25%: R22 – Harmful if swallowed;
  - conc ≥ 20%: R38 – Irritating to skin;
  - conc ≥ 10%: R41 – Risk of serious damage to eyes;
  - 5% ≤ conc < 10%: R36 – Irritating to eyes.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer introduced as a pure substance:
  - Enclosed and automated processes at the blending and packaging sites, including use of semi-automated filling machines and metered pumps;
  - Adequate ventilation for the plant operators.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation and end use:
  - Adequate training for staff in handling noninoic surfactants;
  - Implementation of general health surveillance and monitoring programs as required.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation and end use:
  - Chemical goggles/face shields for plant operators;
  - Industrial standard protective clothing and impermeable gloves for plant operators and cleaning staff;
  - Vapour masks or appropriate respirators if required.

  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 the notified polymer 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.

Disposal

- The notified polymer should be disposed of to secure landfill or incineration.

Emergency procedures

- Spills/release of the notified polymer should be handled by containment with suitable absorbents, collection and storage in a sealable and labelled container for disposal in accord with local regulations.

12.1. Secondary notification

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

(1) Under Section 64(1) of the Act; if
  - Concentration of the notified polymer exceeds 4% in end use products;
  - Import volume exceeds 200 tonnes per annum, it is required a better estimate of the release to the sewer, particularly in the rural areas, and a chronic toxicity test report for *Daphnia magna* be submitted for assessment.

or

(2) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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