File No: PLC/156

July 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in Baygard RT

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Director Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Polymer in Baygard RT

1. APPLICANT

Bayer Australia Ltd (ABN 22 000 138 714) of 633-647 Springvale Road Mulgrave North VIC 3170 has submitted a notification statement in support of their application for an assessment certificate for Polymer in Baygard RT.

2. IDENTITY OF POLYMER

Other names: Baygard FC 73649

Marketing name: Baygard RT

Reactive functional groups:

The notified polymer contains the amine reactive functional group at a low concentration.

Functional group equivalent weight (FGEW): 5866

Structural identification method: IR

3. POLYMER COMPOSITION AND PURITY

Degree of Purity: > 99%

Maximum Content of Residual Monomers:

Chemical Name	CAS No.	Weight %
total residual monomer content		< 0.1%

The identities of impurities, additives and adjuvants have been exempted from publication in the Full Public Report.

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is produced in aqueous solution and is never isolated. The physicochemical properties given below are for a < 10 % aqueous ethanol solution.

Property	Result	Comments
Appearance	white to yellowish liquid	
Boiling point	approximately 80°C	for the solvent ethanol
Density	1000 kg/m^3	
Water solubility	> 250 g/L	a product exists containing the notified polymer at 25 % in aqueous solution
Particle size	not applicable	the notified polymer is always in aqueous solution
Flammability	not flammable	
Autoignition temperature	> 500°C	
Explosive properties	not expected to be explosive	
Stability/reactivity	stable under normal environmental conditions	
Hydrolysis as function of pH	not determined	no hydrolysis expected in the environmental pH range 4 - 9
Partition coefficient	not determined	
Adsorption/desorption	not determined	
Dissociation constant	pK _a approximately 9.81	based on the analogue triethylamine

5.1 Comments on physical and chemical properties

No test reports were provided for the determination of physical and chemical properties.

The notified polymer is cationic and is imported in aqueous ethanol. No data were provided on the water solubility of the polymer. However, the notifier states that the polymer has solubility of at least 25 % as a product containing the notified polymer at a concentration of 25 % is used overseas. The small amount of amine which may be

protonated and the additional hydrophilic monomer may confer some water solubility to the notified polymer, however the fluorocarbon portion (41 % of the notified polymer) will be hydrophobic and reduce solubility. It is probable that the polymer is not truly soluble, but exists as a colloidal dispersion in ethanol/water, stabilised by the cationic protonated amine groups. After drying, the notified polymer as a textile treatment is expected to be insoluble in water and oil.

The partition coefficient was not determined for the notified polymer. However, as the water solubility of the notified polymer is likely to be low, the partition coefficient of the polymer is likely to be high, with the polymer having some affinity for the organic phase.

The adsorption/desorption was not determined for the notified polymer. However, based on the anticipated low water solubility, $\log K_{oc}$ is likely to be high, with the polymer immobile in soils.

6. USE, VOLUME AND FORMULATION

Use:

The notified polymer will be used in formulation of a textile finishing agent.

Manufacture/Import volume:

The notifier estimates that 3 tonnes per annum of product containing notified chemical at a concentration of < 10 % will be imported during the first five years of importation. This is equivalent to 189 kg of notified polymer per annum.

Formulation details:

The notified polymer will be imported as the product Baygard RT, which contains the notified polymer at < 10 % in aqueous ethanol, in 125 kg plastic drums. The notified polymer will be reformulated at one site in Australia to produce the textile finishing agent, containing the notified polymer at 0.5 %. This will be packaged in 200 L plastic lined steel drums or 25 L plastic cubes for transfer to the end use sites. The product will be applied to textiles by spray gun, and will cure by air drying.

7. OCCUPATIONAL EXPOSURE

Exposure Exposure details Controls indicated by notifier

Reformulation

Formulation and Filling Operators (5 workers, 2 hr/day, 30-40 days/year)

dermal, 6.3 % solution

exposure to drips and spills during manual handling of containers on addition to the enclosed blending tank, during sampling of the blend and cleaning of reformulation

general and local exhaust ventilation used; little worker exposure due to the nature of the blending equipment used; coveralls, safety goggles impervious gloves to be worn

equipment

Packaging Operators (3-5 workers, 2 hr/day, 30-40 days/year)

dermal, 0.5 % solution

exposure to drips and spills while connecting and disconnecting transfer hoses and sealing containers

general and local exhaust ventilation used; little worker exposure due to the nature of the blending equipment used; coveralls. safety goggles impervious gloves to be worn

Laboratory Staff (1 worker, 1 hr/day, 30-40 days/year)

dermal. 6.3 %

exposure to small quantities during

laboratory coats and safety glasses

sampling and testing

solution

End use

Product Application (approximately 500 workers, 4 hr/day, daily)

dermal, ocular.

possible widespread exposure while applying the formulation by

ventilated spray booth or good general ventilation

inhalation 0.5 %

spray

impervious gloves, coveralls and self-

contained breathing apparatus

solution

Equipment cleaning (approximately 500 workers, daily)

dermal 0.5 % solution exposure details not supplied; dermal exposure to quantities of formulation expected

coveralls, safety goggles impervious gloves to be worn

Transport and storage

Unloading and Transport of Baygard RT(2-3 workers, 1-2 hr/day, 5 days/year)

small

none

no exposure expected except in the case of an accident involving overalls and safety boots

rupture of containers

Storage of Baygard RT(2-3 workers, 1-2 hr/day, 5 days/year)

none

no exposure expected except in the

overalls and safety boots

case of an accident involving

rupture of containers

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and

Storage of Textile Finishing Agent (2 workers)

none no exposure expected except in the none

case of an accident involving

rupture of containers

8. PUBLIC EXPOSURE

The notified polymer is not available for sale to the public. The potential for public exposure to the notified polymer during transport and use or from disposal is assessed as negligible. Members of the public may make dermal contact with textiles treated with products containing the notified polymer. However exposure is likely to be negligible since the notified polymer will be in a cured state and is unlikely to be bioavailable.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

Spills of the product containing the notified polymer during transport are unlikely, and would only occur in the case of an accident. In the event of spill, appropriate clean up procedures will be implemented.

The notifier estimates that up to 1 % of Baygard RT will remain in the import drums after emptying, equivalent to 1.89 kg of the notified polymer per year. Another 1 % will be lost due to spills and leaks and will be contained by bunding and recovered by the use of absorbent material. Containers and residual polymer will be disposed of to landfill by licensed waste operators.

During the reformulation process, equipment will be rinsed out and washings sent off-site by licensed waste disposal contractors. Washings are expected to total 3-4 kg of the notified polymer per year.

Accidental spills may occur at the warehouse and may result in the release of 1.9 kg of the polymer per year. This waste will be collected by licensed waste disposal contractors.

At end user sites, of which there will be around 500 Australia wide, the notifier has estimated that 10 % of the polymer will be lost through spills and leaks and washed down into the sewer system. Together with loss of 10 % during application (from mopping of floors after application), approximately 20 % of the notified polymer will be released to the sewer system. This is equivalent to 38 kg/year. However, waste estimates supplied by the notifier are very high and applicators, due to commercial imperatives, would try to avoid high levels of waste, and use sheets or newspaper to capture spray wastes.

The notifier states that after air drying, the polymer will be strongly adsorbed onto textile fibres and is unlikely to be released from the textiles. However, the notifier has not FULL PUBLIC REPORT

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provided a mechanism for this behaviour. Based upon examination of the structural formula, there appears to be limited potential for strong cross linking or chemical bonding to the treated articles, so the proportion of polymer released may be higher than expected.

9.2. Fate

The majority of the polymer will be applied to textiles and will share the fate of the treated articles at the end of their useful lives, by disposal to landfill (for the major proportion) or incineration. Residual polymer in import drums, and waste polymer from spills and leaks and equipment cleaning during the reformulation process will also be disposed of to landfill. The notifier has stated that, as a result of end-use application, approximately 20 % of the polymer, equivalent to 38 kg per annum, will enter the sewer.

Any release into the environment of the notified polymer is initially unlikely to become associated with either the aqueous or organic phase, due its low water solubility and its unique hydrophobic and oleophobic nature. Once cleavage of the C-C bond occurs at the site of esterification, the hydrocarbon component is likely to become assimilated with soils, sludges and sediments, while the fluorinated alcohol is likely to persist in the environment.

The major environmental exposure route of the notified polymer is likely be from disposal to landfill, incineration, and discharge of wash waters to the sewage system. On disposal to landfill, the hydrocarbon portion of the polymer will remain bound within the soils and sediments of the landfill to be slowly degraded by biotic and abiotic processes. If incinerated, the polymer would be rapidly destroyed and converted to water vapour and oxides of carbon, nitrogen and hydrogen fluoride (HF).

No biodegradation data was provided, but it is probable that the hydrocarbon portions of the polymer will ultimately biodegrade and be slowly mineralised to water and oxides of carbon and nitrogen. However, the fluorocarbon portion is unlikely to be susceptible to biodegradation (Remde and Debus, 1996) in view of the electronegativity of fluorine and the great strength of the carbon-fluorine bond. Perfluorocarbons are more thermally stable than their corresponding hydrocarbon analogues. In addition to thermal stability, perfluorinated hydrocarbons are stable against degradation by acids, bases, oxidants and reductants (Moody and Field, 2000). Fluorinated carboxylic acids can undergo hydrolytic defluorination, reductive defluorination, and decarboxylation. To date significant defluorination has been observed for hydrolytic attack of monofluorinated carboxylic acids, while compounds of more than one fluorine atom per carbon atom are generally recalcitrant (Blake, 1997). The notified polymer has a high fluorine content (~41 %) and studies have shown that fluorinated compounds with a fluorine content in the order of 50 % will not biodegrade over a period of 60 days (Remde and Debus, 1996). Further, fluorocarbons have little affinity for either water or organic phases and ultimately concentrate near the surface of water bodies, for example when released in sewage treatment plant effluent. They are likely to be degraded by abiotic cleavage, with assistance from UV radiation, into smaller fluorocarbon species, which will be volatile and partition into the atmosphere. Here further reaction with hydroxyl radicals and action by UV radiation is expected to lead to degradation to HF and precipitation to the surface in rain. However, it cannot be ruled out completely that the fluorocarbon species will not take part in the destruction of the ozone layer, as is typical of chlorofluorocarbons.

Although the high molecular weight of the notified chemical would tend to preclude bioaccumulation (Connell, 1990), recent studies have shown evidence of significant accumulation of fluorinated hydrocarbons in the blood of higher trophic level organisms, including humans. The origin of the fluorocarbons is strongly suspected to be anthropogenic, and results from these studies have led a major fluorocarbon manufacturer (3M) to cease production of these compounds (Tullo, 2001). Research funded by 3M found fluorinated compounds in human blood and animal tissue in parts of the world where these are not manufactured (Moody and Field, 2000; Environmental Science and Technology/News, 2000). However, unlike perfluorooctane sulfonate (PFOS, an ingredient of a soon-to-be-discontinued oil and water repellent), which has been found at elevated levels in the tissues of organisms in remote marine regions well removed from major human activity, significant tissue concentrations of perfluorooctanoic acid seem to be far less widespread (Giesy and Kannan, 2001). Laboratory toxicity studies in rats and primates has shown that perfluorinated compounds can cause death in adult monkeys and rat offspring (Renner, 2001). In addition, the US EPA have stated "This widespread presence, persistence and bioaccumulation potential and the reproductive and subchronic toxicity of the chemical (PFOS) raises concerns for potential adverse effects on people and wildlife" (Chemical Regulation Reporter, 2000).

The above comments need to be seen in light of the proposed low quantities of the polymer to be imported, namely < 200 kg polymer consisting of < 100 kg perfluorinated component.

10. EVALUATION OF HEALTH EFFECTS DATA

Toxicity testing has been performed on two formulations, Baygard K (25 % analogue polymer, see below) and Baygard RT (6.3 % notified polymer). While the CAS number specified for Baygard K is different to that for the notified polymer, the difference in name is that the initiator is omitted in the name corresponding to this CAS number, but included in the name of the notified polymer.

10.1 Acute Toxicity

Summary of the acute toxicity of Baygard K

Test	Species	Outcome	Reference
acute oral toxicity	rat	$LD_{50} > 2000 \text{ mg/kg}$	(Bayer AG, 1994b)

skin irritation	rabbit	slight irritant	(Bayer AG, 1994a)
eye irritation	rabbit	slight irritant	(Bayer AG, 1994a)

Summary of the acute toxicity of Baygard RT

Test	Species	Outcome	Reference
skin sensitisation	guinea pig	non-sensitiser	(Bayer AG, 1997)

10.1.1 Oral Toxicity (Bayer AG, 1994b)

Species/strain: rat/Wistar

Number/sex of animals: 5/sex

Observation period: 14 days

Test substance: Baygard K (25 % notified polymer)

Method of administration: gavage, dose level 2000 mg/kg

Test method: similar to OECD TG 401

Mortality: there were no premature decedents during the study

Clinical observations: no clinical signs of toxicity were observed

Morphological findings: no macroscopic abnormalities were observed at necropsy

Comment: the test report was submitted in German; no translation was

provided

 LD_{50} : > 2000 mg/kg

Result: the test substance was of very low acute oral toxicity in rats

10.1.2 Skin Irritation (Bayer AG, 1994a)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 female

Observation period: 14 days

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Test substance: Baygard K (25 % notified polymer)

Method of administration: 500 µL test substance applied by semi-occlusive patch to a

shaved area of the trunk for 4 hr; residual test material was

removed with water

Test method: OECD TG 404

Draize scores:

Time after	Animal #			
treatment (days)	1	2	3	
Erythema				
1 hr	^a 2	0	0	
1	1	0	0	
2	1	0	0	
3	1	0	0	
7	1	0	0	
14	0	0	0	
Oedema	all	Draize scores were	zero	

^a see Attachment 1 for Draize scales

Result: the test substance was slightly irritating to the skin of rabbits

10.1.3 Eye Irritation (Bayer AG, 1994a)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 female

Observation period: 7 days

Test substance: Baygard K (25 % notified polymer)

Method of administration: 0.1 mL test substance was instilled in the conjunctival sac of

one eye; after 24 hr, the treated eye was rinsed with normal

saline; the untreated eye served as control

Test method: OECD TG 405

Draize scores of unirrigated eyes:

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Time after instillation

Animal	1	l hou	r		1 day	,	2	2 day	S		3 day	S		7 day	S
Cornea		all Draize scores were zero													
Iris		all Draize scores were zero													
Conjunctiva	r	c	d	r	c	d	r	c	d	r	c	d	r	с	d
1	¹ 1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
2	1	1	0	2	1	0	1	0	0	0	0	0	0	0	0
3	1	1	1	1	0	0	1	0	0	0	0	0	0	0	0

¹ see Attachment 1 for Draize scales

o = opacity a = area r = redness c = chemosis d = discharge

Result:

the test substance was slightly irritating to the eyes of rabbits

10.1.4 Skin Sensitisation (Bayer AG, 1997)

Species/strain: guinea pig/Hsd Poc:DH

Number of animals: 10 female (test group)

5 female (control group)

Induction procedure:

test group: day 0

on a prepared area of skin from the shoulder region of test animals, three pairs of intradermal injections were administered as follows:

- 1. 0.1 mL of Freund's Complete Adjuvant (FCA) 50 % (v/v) in sterile saline;
- 2. 0.1 mL 5 % Baygard RT in sterile saline;
- 3. 0.1 mL 5 % (w/v) Baygard RT in sterile saline 50 % (v/v) with FCA

day 7

50 % Baygard RT in sterile saline was applied by occlusive patch to the same site that received the intradermal injections for 48 hours

control group:

day 0

on a prepared area of skin from the shoulder region of test animals, three pairs of intradermal injections were administered as follows:

- 1. 0.1 mL of Freund's Complete Adjuvant (FCA) 50 % (v/v) in sterile saline;
- 2. 0.1 mL sterile saline;
- 3. 0.1 mL of FCA 50 % (v/v) in sterile saline

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sterile saline was applied by occlusive patch to the same site that received the intradermal injections for 48 hours

Challenge procedure:

day 21

an occlusive patch containing 0.5 mL of a 40 % concentration of Baygard RT in sterile saline was applied to the shaved left flank of each animal for 24 hr; a similar patch containing vehicle only was applied to the anterior right flank; residual test substance was removed with saline solution

dermal reactions were scored at 24 and 48 hours after patch removal

Test method:

OECD TG 406 (Magnusson and Kligman Method)

Challenge outcome:

	Test a	nimals	Control animals				
Challenge concentration	24 hours*	48 hours*	24 hours	48 hours			
40%	**0/10	0/10	0/5	0/5			

^{*} time after patch removal

Result:

the test substance was not sensitising to the skin of guinea pigs

10.2 Overall Assessment of Toxicological Data

The notified polymer has a high molecular weight (NAMW > 1000) and low reactivity, and is not expected to cross biological membranes. It is of very low acute oral toxicity in rats ($LD_{50} > 2000 \text{ mg/kg}$) and is a slight skin and eye irritant in rabbits. It is not a skin sensitiser in guinea pigs. The formulations containing the notified polymer are not classified as hazardous substances in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b) for these end points. No classification can be made for other toxicity endpoints.

The notifier indicated that fluorocarbon resins, including the notified polymer, may be toxic by inhalation at 100 % as respirable aerosols.

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

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^{**} number of animals exhibiting positive response

The notifier has submitted result summaries only of a German study (in German), conducted by Bayer AG, of the toxicity of the notified polymer towards aquatic organisms and bacteria:

Zebra fish toxicity: $LC_{50} = 5.6 \text{ g/L}$ Bacterial toxicity: $EC_{50} = 6.6 \text{ g/L}$

The Zebra fish LC₅₀ was calculated as a geometric mean, based on measured LC₀ = 3.16 g/L and LC₁₀₀ = 10 g/L. These values refer to nominal concentrations of the notified polymer in water. However, the concentrations are likely to be well in excess of the limit of solubility of the polymer in water.

The bacterial $EC_{50} = 6.6$ g/L was interpolated from mortality due to exposure to concentrations of the notified polymer of 1, 1.8, 3.2, 5.6 and 10.0 g/L. 3,5-Dichlorophenol was used as the reference material. It is not known whether the concentrations referred to in this test are nominal or measured. However, it is likely that these refer to nominal concentrations because of the expected low water solubility of the polymer.

12. ENVIRONMENTAL RISK ASSSESSMENT

Ultimately, most of the polymer will be released to landfill or incinerated with the treated textiles. Significant leaching from the treated material is not expected because of the likely low water solubility of the notified polymer and its affinity for the textile surfaces on which it is expected to be fixed. The majority of wastes generated from the reformulation and application of the polymer will go to landfill. The hydrophobic and oleophobic nature of the polymer suggest that it will initially have little affinity with either organic matter (sediments, soil or sludge) or the aqueous phase. In landfill, the hydrocarbon portions of the polymer will probably be slowly degraded to carbon and nitrogen oxides through abiotic and biotic processes, with the fluorocarbon fraction remaining. If incinerated, the polymer would be rapidly destroyed and converted to water vapour and oxides of carbon, nitrogen and HF.

The reformulation and use of the notified polymer will generate waste polymer, which will be released to the sewer system. Within the sewer system, the hydrocarbon moiety is likely to become assimilated with the organic phase (sediments and sludges), while it is possible that the fluorocarbons will partition to surface waters. The PEC for the notified polymer is based on a national use pattern with 20 % of the notified polymer going to sewer:

Amount of polymer imported per annum: 189 kg
Amount of polymer discharged to sewer (20%): 37.8 kg
National population: 19000000
Daily water usage/person 150 L

PEC: $0.037 \mu g/L$

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The PEC before dilution in receiving waters of 0.037 μ g/L is well below the fish acute toxicity level provided, LC₅₀ = 5.6 g/L.

Given the available data, the overall environmental risk associated with the introduction of the notified polymer at currently estimated levels appears to be low. However, there are uncertainties surrounding the behaviour of fluorocarbon compounds in the environment and these are addressed in the recommendations below.

13. HEALTH AND SAFETY RISK ASSESSMENT

Hazard assessment

The notified polymer is of very low acute oral toxicity in rats ($LD_{50} > 2000$ mg/kg) and is a slight skin and eye irritant in rabbits. It is not a skin sensitiser in guinea pigs. The formulations containing the notified polymer are not classified as hazardous substances in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b) for these end points. No classification can be made for other toxicity endpoints.

The notifier indicated that fluorocarbon resins, including the notified polymer, may be toxic by inhalation at 100 % as respirable aerosols. The Material Safety Data Sheet (MSDS) for the product Baygard RT indicates that skin contact and inhalation of vapours and spray should be absolutely avoided, and the formation of vapour or aerosol on spillage must be absolutely avoided. The MSDS indicates that respiratory equipment is mandatory for all spray applications.

Occupational health and safety

Based on the hazard assessment, there is little occupational risk in handling the notified polymer during transport and storage or reformulation. Dermal or ocular contact with the solution of the notified polymer during these activities may result in some irritation, and protective gloves and eyewear should be used to prevent exposure to the notified polymer.

Workers involved in applying the notified polymer by spraying may be exposed to the notified polymer by inhalation, as well as dermal and ocular contact. Inhalation of the aerosol is expected to lead to deposits of the notified polymer in the lungs, where it may interfere with normal lung function, and resist clearance by the usual mechanisms due to its likely insolubility in both water and lipid phases. While the notified polymer as respirable particles and 100 % concentration may be toxic by inhalation, the notifier indicated that the spray use for the products containing the notified polymer will produce spray particles which are larger than the respirable size range and contain low concentrations of notified polymer.

The product containing the notified polymer should only be applied by spray under conditions of excellent ventilation; regular use should occur only within ventilated spray

booths. Self-contained breathing apparatus should be worn during spray application, and workers not involved in application should remain outside the application area.

Public health

Products containing the notified polymer will not be available to the public. Members of the public may make dermal contact with textile treated with products containing the notified polymer. However, the risk to public health from the notified polymer will be negligible because it is present at low concentrations and is unlikely to be bioavailable after application to textiles.

14. MSDS AND LABEL ASSESSMENT

MSDS

The MSDS of the product containing the notified polymer, Baygard RT, provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

Label

The label for the product containing the notified polymer, Baygard RT, provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

15. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer in the end use products:
 - Spray application of the products containing the notified polymer must be carried out under local ventilation and a spray booth should be used for large or frequent applications.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer in the end use products:
 - Self-contained breathing apparatus must be used when applying the products containing the notified polymer by spraying;
 - Safety goggles, chemical resistant industrial clothing and footwear and impermeable gloves should be used while handling the product containing the notified polymer; where engineering controls and work practices do not reduce vapour and particulate exposure to safe levels, an air fed respirator should also be used.

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

• Disposal of waste should be in accordance with Local, State and Federal government regulations; waste should be disposed of by landfill and incineration; liquid wastes should be pretreated to remove the notified polymer for separate disposal prior to release to the sewer.

15.1 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) <u>Under Section 64(1) of the Act</u>; if

- the notified polymer is introduced in a chemical form that does not meet the PLC criteria; or
- the notifier becomes aware of any new information with respect to (i) the degradation of the notified polymer or (ii) the environmental fate and effects of the notified polymer, or general fluorocarbon analogues; or

 import levels increase above 1 tonne notified polymer per annum, when a revised assessment, including a translation of the aquatic toxicity data, may be required.

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.

16. REFERENCES

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Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize et al., 1944) 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	2 mod.	Obvious swelling with partial eversion of lids Swelling with lids half-	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
easily discernible Diffuse beefy red	3 severe	closed Swelling with lids half- closed to completely closed	3 mod. 4 severe	Discharge with moistening of lids and hairs and considerable area around eye	3 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

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