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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Polymer in Aquaflex XL-30

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**Director
Chemicals Notification and Assessment**

TABLE OF CONTENTS

FULL PUBLIC REPORT	4
1. APPLICANT AND NOTIFICATION DETAILS	4
2. IDENTITY OF CHEMICAL	4
3. COMPOSITION.....	5
4. INTRODUCTION AND USE INFORMATION.....	5
5. PROCESS AND RELEASE INFORMATION.....	6
5.1. Distribution, transport and storage.....	6
5.2. Operation description.....	6
5.3. Occupational exposure.....	6
5.4. Release.....	7
5.5. Disposal	7
5.6. Public exposure.....	8
6. PHYSICAL AND CHEMICAL PROPERTIES.....	8
7. TOXICOLOGICAL INVESTIGATIONS	9
7.1. Acute toxicity – oral	9
7.2. Acute toxicity – dermal.....	11
7.3. Irritation – skin	11
7.4. Irritation – eye.....	12
7.5. Skin sensitisation	12
7.6. Genotoxicity – bacteria	13
7.7. Repeat Insult Patch Test – human volunteers	14
7.8. Phototoxicity – human volunteers	14
7.9. Photoallergy – human volunteers.....	15
8. ENVIRONMENT.....	16
8.1. Environmental fate.....	16
8.2. Ecotoxicological investigations	16
8.2.1. Acute toxicity to fish.....	16
8.2.2. Acute toxicity to aquatic invertebrates.....	17
8.2.3. Algal growth inhibition test	17
9. RISK ASSESSMENT	19
9.1. Environment	19
9.1.1. Environment – exposure assessment.....	19
9.1.2. Environment – effects assessment	20
9.1.3. Environment – risk characterisation.....	20
9.2. Human health.....	21
9.2.1. Occupational health and safety – exposure assessment	21
9.2.2. Public health – exposure assessment.....	21
9.2.3. Human health – effects assessment.....	22
9.2.4. Occupational health and safety – risk characterisation	22
9.2.5. Public health – risk characterisation.....	22
10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS	23
10.1. Hazard classification.....	23
10.2. Environmental risk assessment	23
10.3. Human health risk assessment	23
10.3.1. Occupational health and safety.....	23
10.3.2. Public health.....	23
11. MATERIAL SAFETY DATA SHEET	23
11.1. Material Safety Data Sheet	23
11.2. Label	23
12. RECOMMENDATIONS.....	23
12.1. Secondary notification	24
13. BIBLIOGRAPHY	25

FULL PUBLIC REPORT

Polymer in Aquaflex XL-30

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

ISP (Australasia) Pty Ltd (ABN: 27 000 011 923)
73-75 Derby Street,
SILVERWATER NSW 2141

NOTIFICATION CATEGORY

Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Structural formula;
Polymer constituents;
Hazardous impurities/residual monomers;
Identity of additives/adjuvants;
% Weight of additives/adjuvants;
Number average molecular weight.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Melting point/ Boiling point;
Density;
Vapour pressure;
Water solubility;
Hydrolysis as function of pH;
Partition co-efficient;
Absorption/desorption;
Dissociation constant;
Particle size;
Flash point;
Flammability limits;
Autoignition temperatures;
Explosive properties;
Reactivity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

LVC Permit Number 660

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

2,5-Furandione, polymer with 2-methyl-1-propene, ethyl ester, reaction product with N,N-dimethyl-1,3-propanediamine and polyethylene-polypropylene glycol 2-aminopropyl Me ether

OTHER NAME(S)

Imidised poly (isobutylene-co-maleic anhydride) copolymer;
Polyimide 1
ACP-1311

MARKETING NAME(S)

Polymer in Aquaflex XL30

CAS NUMBER

497926-97-3

MOLECULAR FORMULA

$[-CH_2C(CH_3)_2CH(CO_2R)CH(CO_2R)-][-CH_2C(CH_3)_2CH(COR'OC)CH-]-$,
R=H or OCH_2CH_3 , R'=(CH_3)₂N(CH₂)₃NH or $C_3H_9NO.(C_3H_6O.C_2H_4O)_x.CH_4O$

SPECTRAL DATA

METHOD Infrared (IR) spectroscopy
Remarks Peak at 1116.63, 1146.64, 1370.73, 1401.73, 1486.76, 1696.32, 1766.90, 2871.71, 2953.74 cm^{-1}
TEST FACILITY Not provided.

METHODS OF DETECTION AND DETERMINATION

METHOD Infrared (IR) Spectroscopy
Remarks Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

>99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

A single hazardous monomer is present but not at levels which would render the notified polymer hazardous.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

None.

ADDITIVES/ADJUVANTS

None.

DEGRADATION PRODUCTS

None known.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Not known.

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported into Australia as component of aqueous solution (28-32% notified polymer).

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

Year	1	2	3	4	5
Tonnes	3.5	3.5	3.5	3.5	3.5

USE

The notified polymer is a hair fixative resin, which will be used in hair styling products such as gels, hair styling lotions, cremes, and mousses. The concentration of the notified polymer in the final product will be 0.03 - 2.3%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Local manufacturers of hair care products.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in an aqueous solution in 204.1 kg net weight metal drums. Following reformulation the final product containing the notified polymer will be packaged into 150 mL tubs, 150 mL tubes, 200 g cans and 170 mL spray bottles.

5.2. Operation description

The notified polymer will be imported as a component of the aqueous solution; Aquaflex XL30 (28-32% notified polymer). The aqueous solution will be imported in 204.1 kg net sealed metal drums. Waterside workers will transfer the containers to trucks for transport directly to the reformulation site for storage.

A chemist (QA staff) will sample the solution containing the notified polymer when it is received at the warehouse. After testing and approval, the aqueous solution will be pumped by compounders into tanks and compounded into bulk product. The concentration of the notified polymer in the finished product will be 0.03 to 2.3%. Following further quality control testing the approved bulk product is pumped via automated covered filling lines into individual packs (150 mL tub, 150 mL tube, 200 g cans and 170 mL spray bottles). The individual packs are then packed into 36 unit cartons for retail distribution.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Transport and Warehouse	2	2 hours/day	30 days/year
Laboratory/Quality Assurance	2	7 hours/day	60 days/year
Plant Operators - Weighing and Compounding	4	8 hours/day	60 days/year
Plant Operators – Filling and Packaging	2	2 hours/day	30 days/year
Hairdressing Salon Workers	>1000	1-2 hours/day	100 days/year

Exposure Details

Categories of workers likely to be exposed to the notified polymer are those involved in the transport of notified polymer, warehousing of the notified polymer, quality assurance of the notified polymer, manufacture of the finished products, quality control of the finished products, warehousing, distribution of the finish products, and retail of the finished products.

Transport and warehousing of imported notified polymer

Transport and warehouse workers handling the imported aqueous solution containing to 28-32% notified polymer will be exposed to the notified polymer only in the event of spill due to the accident or leaking drum.

Manufacture of hair styling product

A chemist (QA staff) will sample the aqueous solution containing 28-32% notified polymer when it is received at the warehouse. After testing and approval, the imported aqueous solution will be pumped into tanks by compounders and compounded into bulk product. Dermal and ocular exposure may occur from drips and spills when pumps are connected and disconnected. The concentration of the notified polymer in the finished hair products will be 0.03 to 2.3%. Following further quality control testing the approved bulk product is pumped into automated covered filling lines and filled into their packs (150 mL tub, 150 mL tube, 200 g cans and 170 mL bottle with spray nozzle). The individual packs are then packed into 36 unit cartons for retail distribution. During the QA sampling and dispensing processes, workers may be exposed to drips and spills. The main route of exposure will be dermal.

Worker exposure (including those involved in maintenance and cleaning) will be minimised by the use of protective gloves, coveralls or laboratory coats for QA workers, safety glasses and safety boots. Mixing vessels and the filling machines are located in large factory areas and share the normal factory ventilation.

Transport, warehousing and retail of the finished hairstyling products.

Once reformulated into final products, transport warehouse and retail workers handling the notified polymer will be exposed to 0.03 to 2.3% notified polymer in the case of the accident when the packaging is breached. The main route of exposure will be dermal.

End use of finished hairstyling products

Hairdressers will be dermally exposed to the hair styling products containing the notified polymer (0.03-2.3% notified polymer), while applying the product to hair. It is unlikely that personal protective equipment such as gloves will be used by these workers.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The polymer will be imported into Australia at Sydney, and transported by road to North Rocks, where it will be formulated with other ingredients to produce hair-styling products. Environmental exposure comes from three main routes. The first route of environmental exposure arises from accidental spills. The notified polymer should be contained physically, collected in an absorbent material, and disposed to secure landfill. The second route of environmental exposure arises from the disposal of import containers with residual notified polymer. Only 0.06% of total imported notified polymer is expected to remain in these containers, which will be sent to drum reconditioners. The residual notified polymer will be thermally decomposed in high temperature incinerators. The third route of environmental exposure arises from the wastewater produced from cleaning equipment used in the formulation of the notified polymer. This wastewater is disposed of to a trade waste system and biological processing treatment plant. Once treated, the wastewater is disposed of appropriately through the sewer according to a permit provided by Sydney Water. It is important to note that due to the likely low biodegradability of the notified polymer, it is expected that there will not be any degradation in this process. No data have been provided on the expected quantity of notified polymer to be discharged in this manner.

RELEASE OF CHEMICAL FROM USE

The end-use products containing the notified polymer are applied to hair as a styling agent. Due to its high, but unspecified, water solubility, the notified polymer does not bond permanently to the hair and is washed off during routine hair washing. Apart from the minimal quantity remaining in packaging which will be disposed of in domestic waste to landfill, the majority of notified polymer will be released during hair washing to the sewer, where it is expected to pass through STPs to surface water.

5.5. Disposal

The residual notified polymer in import containers will be thermally decomposed in high temperature incinerators. Wastewater containing notified polymer produced at the site of formulation will be disposed of to a trade waste system and biological processing treatment plant. Once treated, the water is disposed of appropriately through the sewer according to a permit provided by Sydney Water. End-use product packages containing residual notified polymer are expected to be disposed to landfill via domestic waste. The majority of notified polymer will be released to sewer after use by washing of

hair.

5.6. Public exposure

The notified polymer will be used in hairstyling products. The maximum concentration of the notified polymer will be 2.3% by weight. It is expected that the hairstyling products would be used once or twice daily.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	A yellow viscous solution. (imported product)
Melting Point	Not determined.
Remarks	The notified polymer is amorphous with no melting point.
Boiling Point	Not determined.
Remarks	The notified polymer will degrade before boiling.
Density	Not determined.
Remarks	The approximate density for the notified polymer given by the notifier is 1000 kg/m ³
Vapour Pressure	Not determined.
Remarks	The notified polymer is expected to have a very low vapour pressure due to its ionic form.
Water Solubility	Not determined.
Remarks	The notified polymer is expected to be moderately soluble, based on its importation as an aqueous solution of up to 32%, and because the polymer is internally neutralised like a polymeric zwitterion. A pendant dimethyl amino propyl amine (DMAPA) group neutralises carboxylic acid moieties within the polymer. The polymer has been engineered such that the carboxylic acid is matched with pendant amines at a 1 to 1 ratio. This confers water solubility.
Hydrolysis as a Function of pH	Not determined.
Remarks	While there will be no appreciable degradation of the polymer backbone, some hydrolysis of the pendant ester group resulting in elimination of ethanol, and to a lesser extent hydrolysis of the imide, could be expected.
Partition Coefficient (n-octanol/water)	Not determined.
Remarks	Based on its solubility in water a low partition coefficient is expected.
Adsorption/Desorption	Not determined.
Remarks	This is expected to be low due to the water solubility, however any excess N ⁺ ions present will flocculate dissolved organic carbon (DOC) in water (Nabholz et al. 1993).
Dissociation Constant	Not determined.
Remarks	Expected to remain ionised throughout the environmental pH range.
Particle Size	Not determined.

Remarks	The polymer remains in solution until final end use, where it is expected to be held within a gel matrix, before redissolving when end use product is washed off hair.
Flash Point	Not determined.
Flammability Limits	Not determined.
Remarks	The imported product is an aqueous solution without ethanol and is expected to behave like water.
Autoignition Temperature	Not determined.
Remarks	The imported product is an aqueous solution without ethanol and is expected to behave like water.
Explosive Properties	Not determined.
Remarks	The imported product is an aqueous solution without ethanol and is expected to behave like water.
Reactivity	Not determined
Remarks	The notified polymer is expected to stable under normal conditions of temperature and pressure.

7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50>2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence of sensitisation
Genotoxicity – bacterial reverse mutation	non mutagenic
Repeat Insult Patch Test	non-irritating and non-sensitising
Photoallergy	not an irritant or photoirritant and did not induce allergic, or photoallergic contact dermatitis
Phototoxicity	did not induce a response indicative of a phototoxic reaction

7.1. Acute toxicity – oral

TEST SUBSTANCE	ACP-1311 (Lot#PP5582) (30% notified polymer)
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Wistar albino.
Vehicle	None.
Remarks – Method	No significant protocol deviation.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5/sex	2000	0/10
LD50	>2000 mg/kg bw		

Signs of Toxicity	There were no signs of systemic toxicity. All animals showed the expected body weight gains over the study period.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks – Results	None.
CONCLUSION	A 30% solution of the notified polymer is of low toxicity via the oral route.
TEST FACILITY	MB Research Laboratories (2003a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	ACP-1311 (Lot#PP5582) (30% notified polymer)
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rabbit/New Zealand White
Vehicle	None.
Type of dressing	Semi-occlusive.
Remarks – Method	No significant protocol deviation.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5/sex	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Very slight oedema and erythema were observed in one male rabbit at 24 hours. No dermal reactions were observed on days 7 and 14.
Signs of Toxicity - Systemic	Few faeces were observed in one female rabbit on day 13. All animals showed the expected body weight gains over the study period.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks – Results	None.

CONCLUSION	A 30% solution of the notified polymer is of low toxicity via the dermal route.
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TEST FACILITY	MB Research Laboratories (2003b)
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7.3. Irritation – skin

TEST SUBSTANCE	ACP-1311, Lot#PP5582 (30% notified polymer)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None.
Observation Period	72 hours.
Type of Dressing	Semi-occlusive.
Remarks – Method	No significant protocol deviation.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0	0	0	0	-	0
<i>Oedema</i>	0	0	0	0	-	0

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

Remarks – Results	There was no erythema or oedema noted at any observation period. There were no signs of systemic toxicity. All animals showed the normal body weight gains over the study period.
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CONCLUSION	A 30% solution of the notified polymer is non-irritating to the skin.
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TEST FACILITY	MB Research Laboratories (2003c)
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7.4. Irritation – eye

TEST SUBSTANCE ACP-1311, Lot #PP5582 (30% notified polymer)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain Rabbit/New Zealand White

Number of Animals 3

Observation Period 72 hours

Remarks - Method No significant protocol deviation.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0.67	0.33	0.67	1	48 hrs	0
<i>Conjunctiva: chemosis</i>	0	0.33	0	2	24 hrs	0
<i>Conjunctiva: discharge</i>	0	0.33	0.33	2	24 hrs	0
<i>Corneal opacity</i>	0	0	0	0	-	0
<i>Iridial inflammation</i>	0	0	0	1	1 hr	0

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

Remarks - Results

No corneal opacity was observed during the study.

Iridial inflammation was observed in one rabbit at 1 hour and was absent at 24 hours. Hyperemia of conjunctival blood vessels was observed in two rabbits at 1 hour, 24 hours, and 48 hours and in one rabbit at 24 hours only. No redness was observed in any animal at 72 hours.

Chemosis of the conjunctivae was observed at 1 hour in one rabbit and at 1 hour and 24 hours in two rabbits. No chemosis was observed in any animal at 48 hours.

Conjunctival discharge was observed at 1 hour and 24 hours in two rabbits and at 1 hour only in one rabbit. No discharge was observed in any animal at 48 hours.

CONCLUSION

A 30% solution of the notified polymer of the notified polymer is slightly irritating to the eye.

TEST FACILITY

MB Research Laboratories (2003d)

7.5. Skin sensitisation

TEST SUBSTANCE ACP-1311, Lot #PP5582 (30% notified polymer)

METHOD OECD TG 406 Skin Sensitisation – Guinea Pig Maximisation Test (Magnusson-Kligman)

Species/Strain Guinea pig/Hartley Albino

PRELIMINARY STUDY Maximum Non-irritating Concentration:

intradermal: <25%

topical: 50%

MAIN STUDY

Number of Animals

Test Group: 20

Control Group: 10

INDUCTION PHASE	Induction Concentration: intradermal: 25%
Signs of Irritation	topical: 100% No to moderate erythema was observed in the test animals following intradermal and topical induction.
CHALLENGE PHASE	
1 st challenge	topical: 50%
Remarks - Method	No significant protocol deviation.

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after: 1st challenge</i>	
		<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	50%	0/20	0/20
<i>Control Group</i>	50%	0/10	0/10

Remarks - Results	The body weight changes were normal. Diarrhoea and soiling of the anogenital area were noted in two test and two control male rabbits during the observation period.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to a 30% solution of the notified polymer under the conditions of the test.
TEST FACILITY	MB Research Laboratories (2003e)

7.6. Genotoxicity – bacteria

TEST SUBSTANCE	ACP-1311 (Batch PP5582) 30% notified polymer.
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure.
Species/Strain	<i>S. typhimurium</i> : TA98, TA100, TA1535, TA1537. <i>E. coli</i> : WP2uvrA.
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction.
Concentration Range in Main Test	<i>Salmonella</i> strains (Test 1,3,5) a) With metabolic activation: 10.0, 33.3, 100, 333, 1000, 3330, 5000 µg/plate b) Without metabolic activation: 10.0, 33.3, 100, 333, 1000, 3330, 5000 µg/plate <i>Escherichia</i> strains (Test 2,4,6) a) With metabolic activation: 33.3, 100, 333, 1000, 3330, 5000 µg/plate b) Without metabolic activation: 33.3, 100, 333, 1000, 3330, 5000 µg/plate
Vehicle	Water.
Remarks - Method	No significant protocol deviation.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	≥3300		Not provided.	-
Test 2	>5000		Not provided.	-
Test 3		≥3300	Not provided.	-

Test 4		>5000	Not provided.	-
Test 5		>5000	Not provided.	-
Test 6		>5000	Not provided.	-
<i>Present</i>				
Test 1	>5000		Not provided.	-
Test 2	>5000		Not provided.	-
Test 3		≥3300	Not provided.	-
Test 4		>5000	Not provided.	-
Test 5		>5000	Not provided.	-
Test 6		>5000	Not provided.	-

Remarks - Results	All data were found acceptable and no positive increases in the mean number of revertants per plate were observed with any of the tester strains in either the presence or absence of S9 mix.
CONCLUSION	A 30% solution of the notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Convance Laboratories (2003)

7.7. Repeat Insult Patch Test – human volunteers

TEST SUBSTANCE	ACP-1311 Lot#031403 (10% notified polymer)
METHOD	In house protocol.
Study Design	Induction Procedure: Patches were applied three times per week for nine applications. Patches were removed 24 hours after application. Evaluation of the application sites made just prior to re-application. Rest periods consisted of 24 hours following each Tuesday and Thursday removal, and 48 hours following each Saturday removal. Challenge Procedure: Approximately two weeks after the final induction patch application, a Challenge patch was applied to a virgin test site adjacent to the original induction patch site. The patch was removed and site scored at 24 and 72 hours post application.
Study Group	One hundred and twelve qualified male and female subjects ranging in age from 16 to 75 years were selected for this evaluation. One hundred and three subjects completed the study. The remaining subjects discontinued their participation for various reasons, none of which were related to the application of the test material.
Vehicle	None.
Remarks - Method	None.
RESULTS	
Remarks - Results	Observation remained within the normal limits throughout the test interval.
CONCLUSION	A repeat insult patch test was conducted using a 10% aqueous solution containing the notified polymer under semi-occlusive dressing. The solution was non-irritating and non-sensitising under the conditions of the test.
TEST FACILITY	Consumer Product Testing Co. (2003a)

7.8. Phototoxicity – human volunteers

TEST SUBSTANCE	ACP-1311 Lot#031403 (10% notified polymer)
METHOD	In house protocol.
Study Design	The Minimal Erythral Dose (MED) of the unprotected skin of each subject was determined.
	Induction Procedure: On the first day of the study three test sites were identified on the backs of the subjects. Two sites were treated with test product, one was irradiated and one was not irradiated. The third site was not treated and irradiated.
Study Group	Patches were applied to the two sites for 24 hours. The patches were removed and one treated site and one untreated site were irradiated with 0.5 MED of UVB followed by 200 kJoules/m ² of UVA irradiation. All sites were examined at 24 and 48 hours following irradiation. Twelve male and female subjects ranging in age from 18 to 55 years were selected for this evaluation. Twelve subjects completed the study.
Vehicle	None.
Remarks - Method	None.
RESULTS	
Remarks - Results	Observation remained negative throughout the test interval.
CONCLUSION	A phototoxicity study was conducted using a 10% aqueous solution containing the notified polymer under semi-occlusive dressing. The solution did not induce a response indicative of a phototoxic reaction.
TEST FACILITY	Consumer Product Testing Co. (2003b)

7.9. Photoallergy – human volunteers

TEST SUBSTANCE	ACP-1311 Lot#031403 (10% notified polymer)
METHOD	In house protocol.
Study Design	The Minimal Erythral Dose (MED) of the unprotected skin of each subject was determined.
	Induction Procedure: Patches were applied two times per week for three consecutive weeks on duplicate test sites on the lower back of the subjects. Patches were removed 24 hours after application. Any product residue was removed and mechanically induced redness was allowed to abate prior to evaluation. Then, one of the treated sites was irradiated with two times the subject's MED. Test and control were evaluated daily (weekdays) following the initial application for a total of fourteen evaluations.
	Challenge Procedure: Approximately two weeks after the final induction patch application, identical challenge patches were applied to previously unexposed sites and an additional site was outlined for use as a non-treated, irradiated control site. Twenty-four hours later the patches were removed and the sites were evaluated. One of the treated sites and the non-treated control site were then irradiated with 70 to 100 kJ/m ² of UVA exposure (non erythemogenic). All of the challenge sites were evaluated at 24, 48, and 72 hours following irradiation.
Study Group	Twenty – eight male and female subjects ranging in age from 20 to 61 years were selected for this evaluation. Twenty – seven subjects

Vehicle	completed the study. One subject discontinued the study for reason unrelated to the test material.
Remarks - Method	None.
RESULTS	
Remarks - Results	Observation remained negative throughout the test interval.
CONCLUSION	A photoallergy study was conducted using a 10% aqueous solution containing the notified polymer under semi-occlusive dressing. The solution was not an irritant or photoirritant and did not induce allergic, or photoallergic contact dermatitis.
TEST FACILITY	Consumer Product Testing Co. (2003c)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Aquaflex® XL-30
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static.
Species	Rainbow Trout (<i>Oncorhynchus mykiss</i>)
Exposure Period	96 hour
Auxiliary Solvent	None
Water Hardness	36-46 mg CaCO ₃ /L
Analytical Monitoring	Standard analytical monitoring equipment and techniques for pH, dissolved oxygen concentration and temperature were employed. The test substance was not measured.
Remarks – Method	The protocol states that the total dissolved oxygen concentration will not be allowed to drop below 60% of saturation during the test. During the definitive exposure, dissolved oxygen measurements at the 48-hour interval ranged from 5.8–7.0 mg/L (55 to 67% of saturation). As no mortalities or sublethal effects were observed among the fish exposed to the control, this deviation did not have a negative impact on the results of the study. All other parameters were within the guidelines.

RESULTS

Concentration mg(solids)/L		Number of Fish	Mortality				
Nominal	Actual		1 h	24 h	48 h	72 h	96 h
Control		10	0	0	0	0	0
0.41 mg/L		10	0	0	0	0	0
0.81 mg/L		10	0	0	0	0	0
1.6 mg/L		10	0	0	0	0	0
3.3 mg/L		10	0	0	0	3	4
6.5 mg/L		10	0	0	4	9	9
13 mg/L		10	0	0	6	10	10

LC50	>13 mg/L at 24 hours. 9.8 mg/L at 48 hours. 4.1 mg/L at 72 hours. 3.8 mg/L at 96 hours (Nominal, C.I. ₉₅ 2.8 – 5.0 mg/L).
NOEC	1.6 mg/L at 96 hours.
Remarks – Results	One surviving fish exposed to the 3.3 mg/L treatment level exhibited a partial loss of equilibrium, while another surviving fish exposed to this

treatment level exhibited a complete loss of equilibrium. No mortality or adverse effects were observed among fish exposed to the remaining treatment levels or the control. The 96-hour LC50 value for Aquaflex® XL-30 and Rainbow Trout was estimated by probit analysis.

CONCLUSION A 30% solution of the notified polymer is toxic to fish.

TEST FACILITY Springborn Smithers Laboratories (2005a)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Aquaflex® XL-30

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent None

Water Hardness 180 mg CaCO₃/L

Analytical Monitoring Standard analytical monitoring equipment and techniques for pH, dissolved oxygen concentration and temperature were employed. The test substance was not measured.

Remarks – Method No deviations from the protocol occurred during this study. Test concentrations were based on a preliminary study.

RESULTS

Concentration mg(solids)/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control		20	0%	0%
1.8		20	0%	0%
4.1		20	0%	0%
9.1		20	0%	0%
20		20	0%	0%
45		20	0%	0%
100		20	5%	10%

LC50 >100 mg(solids)/L at 48 hours

NOEC 20 mg/L at 48 hours

Remarks - Results Test solutions were observed to be clear and colourless with no undissolved test substance present. Following test termination (48 hours), immobilisation of 10% was observed among daphnids exposed to the 100 mg/L treatment level. In addition, all mobile daphnids exposed to 100 mg/L treatment level were observed to be pale and lethargic. All of the mobile daphnids exposed to the 45 mg/L treatment level were observed to be pale. No immobilisation or adverse effects were observed among daphnids exposed to any of the remaining treatment levels tested or the control. Since no concentration tested resulted in ≥ 50% immobilisation, the 48-hour EC50 for Aquaflex® XL-30 and daphnids was empirically estimated to be > 100 mg/L, the highest nominal concentration tested.

CONCLUSION A 30% solution of the notified polymer is practically non-toxic to daphnids.

TEST FACILITY Springborn Smithers Laboratories (2005b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Aquaflex® XL-30
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	
Exposure Period	72 hours
Concentration Range	Nominal: 0.1, 0.26, 0.64, 1.6, 4.0 and 10 mg/L Actual: Not measured
Auxiliary Solvent	None
Analytical Monitoring	Standard analytical monitoring equipment and techniques for pH, dissolved oxygen concentration and temperature were employed. pH was measured with a Jenco Model 60 pH meter and combination electrode. Dissolved oxygen concentration was measured with a Yellow Springs Instrument (YSI) Model No. 550A dissolved oxygen meter and probe. Daily temperature was measured with a VWR Brand alcohol thermometer. Temperature was continuously monitored throughout this study using a Fisher Scientific Minimum-Maximum thermometer. The test substance was not measured.
Remarks - Method	The protocol states that the test solution temperature will be maintained within $24 \pm 1^{\circ}\text{C}$. Between the 48- and 72-hour observation intervals of the definitive test, the solution temperature ranged from 21 to 23°C due to a malfunction of a circulation fan. The test temperature was within the required range prior to that time interval. Since the 72-hour mean cell density in the control (149.78×10^4 cells/mL) exceeded the required 16-fold increase from the initial cell density (1.0×10^4 cells/mL), this deviation did not affect the results of this study.

RESULTS

<i>Biomass</i>		<i>Growth</i>	
<i>E_bC50</i>	<i>NOEC</i>	<i>E_rC50</i>	<i>NOEC</i>
1.3 mg(solids)/L	0.64 mg(solids)/L	> 10 mg(solids)/L	0.64 mg(solids)/L

Remarks - Results	<p>Throughout the exposure, cells exposed to the treatment levels tested and the controls were observed to be normal. The 72-hour cell density in the control averaged 149.78×10^4 cells/mL. Cell densities in the 0.10, 0.26, 0.64, 1.6, 4.0, and 10 mg/L treatment levels averaged 132.00, 139.75, 151.11, 58.75, 34.42, and 14.08×10^4 cells/mL, respectively.</p> <p>The 0- to 72-hour total biomass in the control averaged 101.67×10^4 cells days/mL. Total biomass in the 0.10, 0.26, 0.64, 1.6, 4.0, and 10 mg/L treatment levels averaged 94.39, 100.40, 95.61, 32.08, 20.12, and 10.32×10^4 cells/mL, respectively. Based on the results of Shapiro-Wilks and Bartlett's Tests, this data set passed the requirements for normality and homogeneity of variance, therefore, Williams' Test was used to determine treatment-related effects. A significant reduction in total biomass was determined at treatment levels ≥ 1.6 mg/L as compared to the control data.</p> <p>The 0- to 72-hour average growth rate in the control averaged 1.74 days^{-1}. The 0- to 72- hour average growth rate in the 0.10, 0.26, 0.64, 1.6, 4.0, and 10 mg/L treatment levels averaged 1.69, 1.70, 1.74, 1.41, 1.21 and 0.91 days^{-1}, respectively. Based on the results of Shapiro-Wilks and Bartlett's Tests, this data set passed the requirements for normality and homogeneity of variance, therefore, Williams' Test was used to determine treatment-related effects. A significant reduction in average growth rate was determined at treatment levels ≥ 1.6 mg/L as compared to the control data. Based on these results, the NOEC for growth rate was determined to be 0.64 mg/L. Since no concentration tested resulted in $\geq 50\%$ inhibition in growth rate compared to the control, the 72-hour <i>E_rC50</i> was empirically estimated to be > 10 mg/L, the highest concentration</p>
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tested.

CONCLUSION

A 30% solution of the notified polymer is toxic to algae.

TEST FACILITY

Springborn Smithers Laboratories (2005c)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Aquaflex XL30 is an aqueous solution containing 28–32% notified polymer. It is a minor ingredient of hair styling products including hair gels, lotions, cremes and mousses. The product does not bond permanently to hair, and is in fact washed off during normal hair washing. Therefore, apart from the minimal residual quantities of notified polymer remaining in containers, which are disposed of to landfill, nearly all of the imported notified polymer will be released to the aquatic compartment via the sewerage system.

The high water solubility and estimated low $\log P_{ow}$ indicates that the majority of the notified polymer will favour the aqueous phase. Residual notified polymer disposed to landfill is likely to associate with soil and sediment and although not readily biodegradable, should degrade through biotic and abiotic process.

Based on maximum annual imports of 3500 kg per annum, and assuming a worst-case scenario that all of this is eventually released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 9.59 kg/day. Assuming a national population of 20.1 million and that each person contributes 200 L/day to overall sewage flows, the worst-case predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated to be 2.385 µg/L. Based on the respective dilution factors of 1 and 10 for inland and ocean discharges of effluents, the PECs of notified polymer in fresh water and marine water will be 2.385 and 0.239 µg/L, respectively.

The SIMPLETREAT model (European Commission, 2003) was used to model the partitioning and losses in sewage treatment plants (STP) throughout Australia. A worst-case scenario was assumed with a very low Henry's Constant ($\log H \leq -4$) and the estimated $\log K_{ow}$, (also a limit value of < -1.0). The SIMPLETREAT table for polymers that are not biodegradable was used to approximate the partitioning behaviour of the notified polymer.

The results obtained indicate that when the polymer is released into the aqueous phase of a STP, approximately 0% is released to air through volatilisation, 100% (3500 kg) partitioned to water and 0% partitioned to biosolids. The resulting PECs for the aquatic environment from the nationwide release of the notified polymer into the sewage systems therefore, will also be the same as those derived for the above worst-case scenario. These PEC values are used in the following risk assessment. However, it should be noted that the notified polymer may be adsorbed by sludge during sewage treatment if pH conditions allowed an excess of N^+ . This has not been accounted for in the use of the SIMPLETREAT model.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m³). Using these assumptions, irrigation with a concentration of 2.385 µg/L may potentially result in a soil concentration of approximately 0.02 mg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 0.12 mg/kg and 0.24 mg/kg, respectively.

The potential for the notified polymer to bioaccumulate is low due to its high NAMW and high water solubility and also will be limited due to the diffused release to sewer Australia wide.

Aquaflex XL30 is imported into Australia via Sydney, in an aqueous solution stored in 204.1 kg

(Net Weight) sealed steel drums, containing a 28 - 32% notified polymer. From port, it is transported by road to the manufacturer at North Rocks. Potential environmental exposure arises from accidental spills from mishandling of drums by operators, or transport vehicle accident.

On arrival at the manufacturing plant, the drums are sampled for quality control and after passing are emptied into a “compounder” mixing vessel. Residual notified polymer remaining in the empty steel drums is expected to be 0.06% (or 2.1 kg) of total imported quantity. The empty drums and drums that fail quality control will be sent to a drum reconditioning plant where residual notified polymer is expected to be thermally decomposed in a high temperature incinerator to form oxides of hydrogen, carbon and nitrogen.

After other ingredients have been added to the “compounder”, the final products are expected to contain 0.03 – 2.30% (w/w) notified polymer. These final products are then pumped directly into consumer packages.

Potential environmental exposure arises from the cleaning and decontamination process of the “compounder” and associated equipment including small package filling equipment. Rinses from these systems are disposed of to a trade waste system and biological processing treatment plant. Once treated, the water is disposed of appropriately through the sewer according to the permit provided by Sydney Water. It is important to note that due to the low biodegradability of the notified polymer, it is expected that there will not be any degradation in this process. No data have been provided on the expected quantity of notified polymer to be discharged in this manner. Accidental spills should be physically contained onsite, collected with absorbent material, and disposed of to secure landfill.

The small packages containing 0.03 – 2.30% of the notified polymer are then shipped in cartons containing 36 packs for retail sale. The products are used as hair gels, lotions, cremes and mousses. The end products are applied to hair, and are washed out during normal hair-washing. Therefore, the ultimate fate of the product is discharge into sewer, where the notified polymer is expected to remain in solution, and pass through STPs into the waterways. No information has been provided regarding the quantity of residual notified polymer within the empty small packs, but due to the low initial concentration, this is expected to be negligible. It is expected that these small packages will be disposed of in domestic waste or to landfill.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below.

Organism	Duration	End Point	mg/L dry matter
Fish	96 h	LC ₅₀	3.8
Daphnia	48 h	EC ₅₀	>100
Algae	72 h	E _b C ₅₀ (Biomass)	1.3
	72 h	E _r C ₅₀ (Growth)	>10

A predicted no effect concentration (PNEC - aquatic ecosystems) of 13 µg/L has been derived by dividing the end point of 1.3 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

9.1.3. Environment – risk characterisation

The risk quotient (RQ) values (PEC/PNEC) for the aquatic environment were determined as follows.

Location	PEC [#] µg/L	PNEC µg/L	RQ
<u>Australia-wide STPs</u>			
Ocean outfall	0.24	13	0.018
Inland River	2.39	13	0.183

PEC and the RQ values calculated assuming that the notified polymer is not removed during sewage treatment.

PEC is calculated to be 2.385 µg/L for freshwater release from STP's. A risk quotient was calculated based on a safety factor of 100. The Q value was determined to be 0.183 for rivers. Given the diffuse and widespread use of the end-use products, the concentration of the notified polymer in the aquatic compartment is likely to be low. Furthermore, the low Q values indicate that there is unlikely to be an environmental risk to the aquatic compartment.

It is expected that any waste generated during use will be disposed of to landfill. In landfill the notified polymer contained in containers is expected to degrade very slowly via biotic or abiotic processes. Therefore, environmental risk from the reported use pattern of the notified polymer is likely to be low.

Based on the proposed use pattern the notified polymer is not expected to pose an unacceptable risk to the health of aquatic life. Bioaccumulation is not expected from the diffuse use pattern.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Exposure to imported aqueous solution containing the notified polymer.

Significant exposure to the imported solution is expected for formulators and QC workers. However, worker exposure will be minimised by use of the appropriate personal protection equipment. Workers involved the formulation process will wear would wear coveralls or laboratory coats, gloves, safety glasses and safety boots. Local exhaust ventilation will be used.

Exposure to finished products containing the notified polymer

Significant exposure to the finished product will be expected for hairdressers. Hairdressers may have repeated dermal exposure to the notified polymer when apply hair styling to customers.

9.2.2. Public health – exposure assessment

The public will be exposed to low levels of the notified polymer via wide range of hairstyling products. Generally hairstyling products are used twice a day.

The public will be dermally exposed to the notified polymer, while accidental ocular exposure and ingestion may also occur.

Members of the public will be exposed to the hair styling products containing the notified polymer, while applying the product to hair. The estimated exposure is calculated below. The estimated exposure is based on the twice a day use of the product, a partition coefficient (amount of product that applied to scalp and hair) to scalp of 10%. Dermal absorption is unlikely due the molecular weight of the notified polymer.

A = maximum amount of product applied (mg)

C = maximum concentration of the notified polymer in products (%)

PC = "Partition coefficient" to scalp for non resin off hairstyling products (%)

F = frequency of application per day

BW = bodyweight (kg)

A = 5000 mg*
C = 2.3%
PC = 10%*
F = 2/day
BW = 60 kg*

(* in SCCNFP (2000))

$$\begin{aligned}\text{Exposure} &= \frac{A \times C \times PC \times F}{BW} \\ &= \frac{5000 \times 2.3\% \times 10\% \times 2}{60} \\ &= \frac{5000 \times 0.023 \times 0.1 \times 2}{60} \\ &= 0.38 \text{ mg/kg bw/day.} \\ &\simeq 0.4 \text{ mg/kg bw/day.}\end{aligned}$$

Direct public exposure during transport and storage or from manufacturing waste is unlikely.

9.2.3. Human health – effects assessment

The notified polymer, tested as a 30% aqueous solution, has low acute oral and dermal toxicity in rats. The notified polymer is non-irritating to the skin of the rabbit, and was not a skin sensitizer in the guinea pig maximisation test. The notified polymer was slightly irritating to the eye of the rabbit. The notified polymer was found not to be mutagenic in a bacterial reverse mutation test.

A 10% aqueous solution of the notified polymer was found to be non - irritating and non - sensitising in a repeat insult patch test in human volunteers. The 10% aqueous solution was found not to be an irritant or photoirritant, and did not induce a reaction indicative of allergic, or photoallergic contact dermatitis in a photoallergy study in human volunteers. The 10% aqueous solution was also found not to induce reactions indicative of phototoxicity in human volunteers.

Based on the available data, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002).

9.2.4. Occupational health and safety – risk characterisation

Due to the high molecular weight of the notified polymer, dermal and oral absorption is unlikely. The low volatility of the notified polymer will restrict the possibility of exposure through inhalation. Although the notified polymer was found to be slightly irritating to eyes in rabbits exposure of workers is minimised by the use of safety glasses, gloves, and overalls.

Once the final consumer product is packed, exposure should be low. Hence, exposure for warehousing and distribution workers and retail workers is unlikely unless the packaging is breached.

Hairdressers will have regular dermal exposure to the notified polymer during use of the hairstyling products. It is unlikely that hairdressers will use gloves during the application of the styling product. The risk for these workers arising from the notified polymer is expected to be low due to its low concentration in the product, its expected low dermal absorption potential and low hazard.

9.2.5. Public health – risk characterisation

The levels of the notified polymer in finished consumer products ranges from 0.03 to 2.3%. Due to the high molecular weight of the polymer dermal and oral absorption is unlikely. The

low volatility of the notified polymer will preclude the possibility of exposure through inhalation. The estimated exposure for members of the public using the products containing notified polymer, will be 0.4 mg/kg bw/day. The estimated exposure is based on the twice a day use of the product, a partition coefficient (amount of product that applied to scalp and hair) to scalp of 10%. Dermal absorption of the notified polymer is unlikely due to molecular weight of the notified polymer.

The risk for public arising from the notified polymer is expected to be low due to its low hazard and the estimated low exposure.

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

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

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 should be classified as Chronic Category II for the environment endpoints. The notified polymer is not classified as hazardous under GHS for the human health points.

10.2. Environmental risk assessment

On the basis of the $PEC_{River}/PNEC$ ratio, the 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 as described in the notification statement.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is 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 provided by the notifier was 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

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
 - Avoid drips and spills.
 - Avoid contact with the eyes.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Safety glasses, coveralls and gloves.

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 by thermal decomposition in a high temperature incinerator or to secure landfill.

Emergency procedures

Spills/release of the notified polymer should be handled by physical containment and subsequent disposal by thermal decomposition in a high temperature incinerator or to secure landfill.

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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