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May 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

2-Propenoic Acid, 2-Methyl-, Polymer with 1,1-Dimethylethyl 2-Propenoate and Ethyl 2-Propenoate
(Luvimer 100P)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Ageing.

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Director
Chemicals Notification and Assessment

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2-Propenoic Acid, 2-Methyl-, Polymer with 1,1-Dimethylethyl 2-Propenoate and Ethyl 2-Propenoate
(Luvimer 100P)

1. APPLICANT

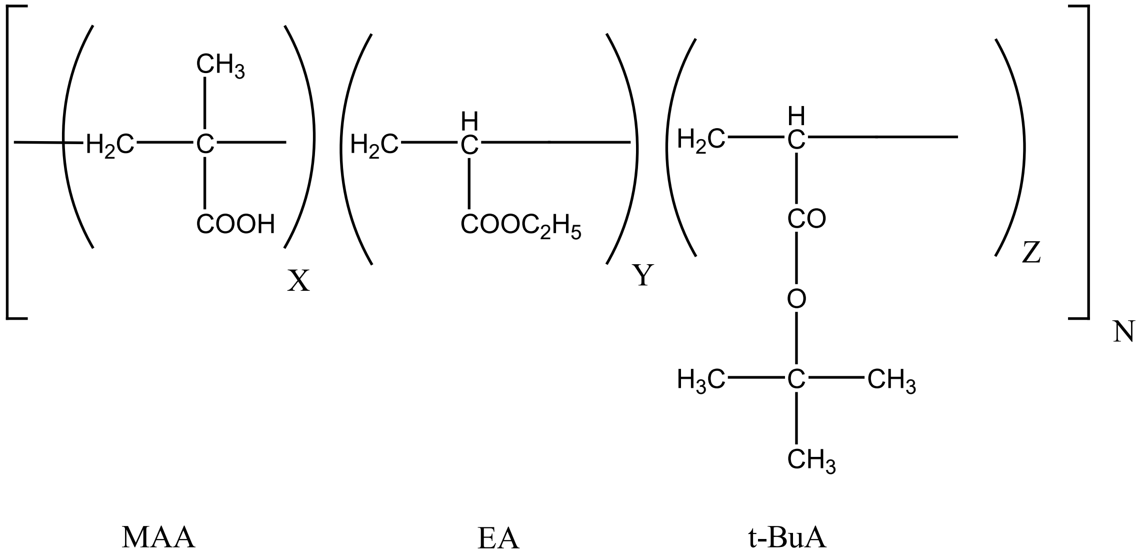
BASF Australia Ltd of 500 Princes Highway NOBLE PARK VIC 3174 (ACN 008 437 867) has submitted a limited notification statement in support of their application for an assessment certificate for Luvimer 100P**.**

2. IDENTITY OF THE CHEMICAL

The molecular weight, spectral data, details of the polymer composition, purity and impurities have been exempted from publication in the Full Public Report and the Summary Report.

Chemical Name:	2-Propenoic acid, 2-methyl-, polymer with 1,1-dimethylethyl 2-propenoate and ethyl 2-propenoate.
Chemical Abstracts Service (CAS) Registry No.:	159666-35-0
Other Names:	tert-Butyl acrylate, ethyl acrylate, methacrylic acid copolymer; Acrylates copolymer.
Marketing Name:	Luvimer 100P
Molecular Formula:	$(C_4H_6O_2)_X . (C_5H_8O_2)_Y . (C_7H_{12}O_2)_Z$

Structural Formula:



X = 2.67 N = 21 (approximately)
Y = 1
Z = 5.2

Comments on Chemical Identity

The notified polymer is a high molecular weight polyacrylic material having significant polydispersity. Polymerisation would be through a free radical mechanism initiated by the peroxodisulphate, small amounts of which remain in the final polymer. Pendant ester functionalities are on every alternate carbon of the polymer backbone chain, and the stoichiometry indicated above was derived on the basis of the Number Average Molecular Weight (NAMW) and % weight of the three acrylic monomers provided by the company. Methacrylic acid residues comprise 23% by weight of the polymer, and in an aqueous environment these anionic groups are likely to give the polymer molecules a significant negative charge, and some affinity for water. The Functional Group Equivalent Weight (FGEW) of the carboxylate functionality in the polymer is estimated at 995 g/mole.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	A free flowing white powder with a weak odour.
Melting Point:	Not determined.
Specific Gravity:	400 kg/m^3
Vapour Pressure:	Not determined.
Water Solubility:	When totally neutralized it can be dissolved in water at 180 g/L.

Partition Co-efficient

(n-octanol/water):	Not determined.
Hydrolysis as a Function of pH:	Not determined.
Adsorption/Desorption:	Not determined.
Dissociation Constant:	Not determined.
Particle Size:	Mean particle size is 46 μm with 2.5% less than 7.78 μm (respirable fraction).
Flash Point:	Not determined.
Flammability Limits:	Not determined.
Autoignition Temperature:	Not determined.
Explosive Properties:	Not explosive.
Reactivity/Stability:	Stable.

3.1 Comments on Physico-Chemical Properties

The high molecular weight and polydispersity of the polymer indicates that it would not have a well defined melting point, would probably decompose prior to melting, and would have very low vapour pressure.

The polymer contains a high content of methacrylic acid groups (23%) which are expected to be fully ionised under environmental conditions, conferring the polymer a substantial negative charge and affinity for water. The notifier indicated that when fully ionised the polymer is dispersible in water with an apparent "solubility" of 18 g/L. The hydrophobic ethyl acrylate (10%) and t-butyl acrylate (67%) residues would counteract the hydrophilic carboxylic acid groups. It is likely that the polymer forms colloidal solutions rather than being truly soluble. At low pH the carboxylate residues would be partially neutralised, reducing the overall anionic charge and substantially decreasing the water solubility.

The pendant ester groups would be susceptible to hydrolysis under extreme pH, but hydrolysis is considered unlikely at normal environmental pH 4-9.

The partition coefficient was not provided. As the carboxylate groups are expected to provide significant affinity for water, the polymer is expected to have little tendency for the oil phase (except perhaps at very low pH where the acid groups will be neutralised) and the partition coefficient is expected to be low.

No adsorption/desorption data was provided. It is not clear whether the material would have any truly physico-chemical basis for adsorbing onto soil or sediments. However, the carboxylate groups will have a high affinity for both calcium and magnesium ions which are usually present in significant concentrations in environmental waters, and on complexing with these ions the polymer would become an electrically neutral insoluble polymeric salt.

This material would be hydrophobic and expected to have high affinity for the organic component of soils and sediments.

No dissociation constant data was provided. The methacrylic acid groups are likely to give the material a pKa of 4-5. The carboxylic acid groups could dissociate under environmental pH making the polymer anionic.

4. PURITY OF THE CHEMICAL

Degree of Purity:	High.

Hazardous Impurities:

Chemical name:	tert-Butanol
Synonyms:	2-methylpropan-2-ol
CAS No.:	75-65-0
Weight percentage:	0.001
Toxic properties:	Highly flammable; harmful by inhalation (NOHSC, 1999a). It has NOHSC exposure standard of TWA (100 ppm or 303 mg/m^3) and STEL (150 ppm or 455 mg/m^3) (NOHSC, 1995).

Chemical name:	Toluene
CAS No.:	108-88-3
Weight percentage:	<0.0002
Toxic properties:	Highly flammable; harmful by inhalation (NOHSC, 1999a). It has NOHSC exposure standard of TWA (100 ppm or 377 mg/m^3) and STEL (150 ppm or 565 mg/m^3) (NOHSC, 1995).

Non-hazardous Impurities (> 1% by weight):	None.
Additives/Adjuvants:	<5% in total, none are listed as hazardous substances (NOHSC, 1999a).
Degradation Products:	No data provided.
Loss of Monomers, Additives, Impurities:	None expected.

5. USE, VOLUME AND FORMULATION

Luvimer 100P is an anionic polymer and will be used as a film forming agent in the production of hair care products, particularly hair sprays, hair mousse and hair lotion, in the cosmetics manufacturing industry.

Estimated import quantities of Luvimer 100P for the first 5 years is 10-20 tonnes per annum.

The notified polymer is imported into Australia as a powder in 25 kg high density polyethylene drums. It will be formulated into hair care products at several sites. An aerosol spray can (250-370 mL) contains 6-8% (or 9.6-21.6 g) Luvimer 100P. The content of residual monomers is below 0.1% or 9.6-21.6 mg per can.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
It is estimated that 1-2 transport workers, 1-2 store workers at the notifier's warehouse and 1-2 workers at customers' warehouse will be involved in handling the notified polymer. The notifier estimated that they will handle the drums for approximately 15 minutes per delivery. These workers are not expected to be exposed to the polymer except in the case of an accident involving spillage.

Formulation
It is estimated that 1-2 operators will be involved in the formulation processes for up to 15 minutes per day. The formulation workers will handle both the notified polymer and the final products. The notified polymer, as a powder packed in 25 kg drums, will be weighed and transferred into an agitated mixing tank, where it will be blended with other ingredients such as moisturisers, emulsifiers, fragrance and preservatives in an aqueous solution to produce the final product, predominantly hair sprays. The final product, an aerosol spray can contains 6-8% Luvimer 100P. The content of residual monomers in the can is below 0.1%. If a propellant is to be used, the final solution is then mixed with the propellant, which comprises either propane/butane or propane alone. Each batch is then transferred to an automated filling machine.

Automatic weighing is employed where possible. However, ingredients may be weighed and added manually. Dermal exposure to the notified polymer is possible during the weighing and adding processes. Both dermal and inhalation would be the main routes for occupational exposure. Cleaning and maintenance of the equipment may involve dermal exposure to the diluted final product.

Local exhaust ventilation is fitted for the removal of vapours at the mixing and filling points where natural ventilation is considered to be inadequate. Formulation workers are expected to wear overalls, safety glasses/chemical goggles and face shields, protective gloves. An air-purifying (dust) respirator may be used if breathable dust is formed.

Laboratory
One to two laboratory technicians will handle the notified polymer for approximately 30 minutes each. They will sample the polymer before and after formulation for quality control. The quantities handled would be small. Laboratory facilities such as fume hoods would be available when required. The staff will wear laboratory coats and safety glasses.

Retail
Retail activities involving the notified polymer will be widespread, but no exposure is expected as the notified polymer will be in the form of the diluted consumer product in sealed aluminium cans.

Hairdressing Industry
There is potential for both dermal and inhalational exposure to the notified polymer through use of products containing this polymer by hairdressers. The frequency of exposure for hairdressing workers will be much greater than that for the general public.

7. PUBLIC EXPOSURE

There is little potential for public exposure to the notified polymer during import, storage, transport or formulation of the hair care products. Disposal of waste polymer after accidental spillage during transport or from processing operations is expected to be carried out in accordance with existing regulations, which will minimise public exposure.

There will be significant public contact with the notified polymer in the form of hair sprays, hair mousse and hair lotion. For each 5-second spray of such a product, the notifier estimates that approximately 0.1 to 1.5 grams of the polymer will be released, depending upon the formulated product. The released polymer will be deposited on hair, and clothing, floors, fittings and furnishings. However, the concentration of Luvimer 100P in hair care products will be low (mostly up to 5%), and it is a stable high molecular weight polymer, which would be expected to be poorly absorbed across biological membranes.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Release of the notified polymer during product manufacture will be low. Occasionally the agitated tanks used for product manufacture are washed out, and the wash water is treated at on-site treatment plants where the polymer residue is expected to associate with the sludge and be placed into landfill.

The notifier estimates that approximately 40 kg of polymer annually may remain in the emptied drums, and sent to landfill with the containers.

The majority of the material will be eventually released as a consequence of its use in consumer products. Most is expected to be released to sewage systems following personal hygiene and general laundry activities.

Some hairspray may remain unused in partially emptied cans and disposed of with these in domestic garbage to landfill. No estimate of the residuals remaining in the cans was provided, but in the worst case scenario where 10% of the spray may remain in the cans, between 1 and 2 tonnes of the polymer may be released to landfill each year (between 1.5 and 3 grams in each discarded spray can). However, this release would occur throughout Australia and would be diffuse and at low levels.

8.2 Fate

Most of the notified polymer will be released into sewage where it would chemically combine with calcium and magnesium forming an insoluble neutral organic salt. However, due to the high proportion of hydrophobic residues (t-butyl and ethyl acrylate groups) the resultant material is expected to associate with the organic component of sewage sludge in the sewer pipes and at the treatment plants and would probably be immobile.

If it is assumed that 90% of the polymer is released to sewer, 9-18 tonnes would be released into sewage each year and associate with the sediment. No biodegradation data has provided for assessment. Once adsorbed into sewer sediment or sludge, the polymer is expected to undergo slow degradation through abiotic and biological processes and degrade to carbon dioxide and water or possibly methane in anaerobic environments. A similar fate is expected for the material released to landfill as spray can residue (1-2 tonne per annum) or waste from the cosmetic manufacturing process.

Small amount of the polymer may be released to receiving waters, where it would complex with metals and assimilate into sediments. Since the polymer has a high molecular weight (21,000 g/mol) it is expected to have low potential for bioaccumulation (Connell, 1989).

9. EVALUATION OF TOXICOLOGICAL DATA

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

9.1 Acute Toxicity

Summary of the acute toxicity of Luvimer 100P

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50}>2 000 mg/kg	Kirsch, 1994
acute inhalation toxicity	rat	LC_{50}>5.2 mg/L	Gamer, 1994
skin irritation	rabbit	A moderate skin irritant	Rossbacher, 1994a
skin irritation	rabbit	Slight skin irritant	BASF, 2002
eye irritation	rabbit	Not an eye irritant	Rossbacher, 1994b
skin sensitisation	guinea pig	Not a skin sensitiser	Kuhlem, 1997

9.1.1 Oral Toxicity (Kirsch, 1994)

Species/strain:	Rat/Wistar
Number/sex of animals:	5/sex

Observation period: 14 days.

Method of administration: A single oral dose (2 000 mg/kg) by gavage (vehicle: aqua bidest).

Test method: OECD TG 401

Mortality: None.

Clinical observations: Males showed impaired general state, dyspnoea and piloerection, and females showed stagnation of body weight.

Morphological findings: None.

Comment: None.

LD_{50}: > 2 000 mg/kg

Result: The notified polymer was of very low acute oral toxicity in rats.

9.1.2 Inhalation Toxicity (Gamer, 1994)

Species/strain: Rat/Wistar

Number/sex of animals: 5/sex

Observation period: 14 days.

Method of administration: The notified polymer was administered as a liquid aerosol (5.2 mg/L) with a mass median aerodynamic diameter (MMAD) of 1.4 µm (in respirable size range) via a head-nose inhalation system to animals for 4 hours.

Test method: OECD TG 403

Mortality: None.

Clinical observations: None.

Morphological findings: None.

Comment: Body weight gain was observed in the study.

LC_{50}: > 5.2 mg/L

Result: The notified polymer was of very low acute inhalational toxicity in rats.

9.1.3 Skin Irritation (Rossbacher, 1994a)

Species/strain:	Rabbit/White Vienna
Number/sex of animals:	2 males and 1 female.
Observation period:	15 days.
Method of administration:	A single dermal of 0.5 g notified polymer (moistened with distilled water) applied to the intact skin under a semi-occlusive dressing for 4 hours.
Test method:	OECD TG 404

Draize scores:

Animal #	***Time after treatment*** ***1 hour***	***24 hours***	***48 hours***	***72 hours***	***8 days***	***15 days***
Erythema						
1	[a]1	2	2	2	1S	1S
2	2	2S	2SS	2SS	1S	1S
3	1	1	1	0	0S	1S
Oedema						
1	1	1	0	0	0	0
2	1	0	0	0	0	0
3	0	0	0	0	0	0

[a] see Attachment 1 for Draize scales
S scaling
SS severe scaling

Comment:	The mean value of Draize scores for erythema was 2 in two animals at the reading times of 24, 48 and 72 hours. In an amendment to the test report, it was claimed by the study director that the skin lesions observed were due to mechanical effects caused by moistening the test substance with water, resulting in adhesive effects.
Result:	The notified polymer was a moderate irritant to the skin of rabbits.

9.1.4 Skin Irritation (BASF, 2002)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	2 males and 1 female.

Observation period: 7 days.

Method of administration: A single dermal of 0.5 g notified polymer (moistened with Miglyol 812N) applied to the intact skin under a semi-occlusive dressing for 4 hours.

Test method: OECD TG 404

Draize scores:

Animal #	***Time after treatment*** ***1 hour***	***24 hours***	***48 hours***	***72 hours***	***7 days***
Test material (right flank) ***Erythema***					
1	0	0	0	0	
2	0	0	0	0	0
3	0	2	1	0	
Oedema	Zero scores for all animals during 7 days.				
Vehicle (left flank) ***Erythema***					
1	1	1	1	0	
2	2	2	2	1	0
3	1	2	1	0	
Oedema	Zero scores for all animals during 7 days.				

Comment: The mean value of Draize scores for erythema was 1 for animal 2 at the reading times of 24, 48 and 72 hours after treated with the notified polymer.

The mean values of Draize scores for erythema was 0.7, 1.7 and 1, respectively for the 3 animals 2 at the reading times of 24, 48 and 72 hours after treated with the vehicle. Erythema in animal 2 was found beyond the area of exposure at 24 hours after treatment with the vehicle.

This second study for skin irritation was conducted due to irritation observed in the first study (section 9.1.3). As it was claimed that the effects observed in the first study were due to mechanical adhesive effects caused by water, an organic solvent (Miglyol 812N) was used in the repeat study.

Result: The notified polymer was a slight irritant to the skin of rabbits.

9.1.5 Eye Irritation (Rossbacher, 1994b)

Species/strain: Rabbit/White Vienna

Number/sex of animals: 1 male and 2 females.

Observation period: 72 hours.

Method of administration: A single dose (0.1 mL, approximately 32 mg) applied to the conjunctival sac of the right eyelid.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

Time after instillation

Animal	***1 hour***			***24 hours***			***48 hours***			***72 hours***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	0	0	0	0	0	0	0	0	0	0	0
2	1	0	0	0	0	0	0	0	0	0	0	0
3	1	0	0	1	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales

r = redness c = chemosis d = discharge

The Draize scores for cornea and iris were zero up to 72 hours.

Comment: No clinical symptoms were observed.

Result: The notified polymer was not irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation (Kuhlem, 1997)

Species/strain: Guinea pig/Hartley

Number of animals: Test group: 20 females;
Control group 1 (challenge): 10 females;
Control group 2 (rechallenge): 10 females.

Induction procedure:

test group: day 0, 7 and 14 — Topical Inductions:
Dermal inductions of 50% notified polymer in water (0.5 mL) were applied under an occlusive dressing on left flank site of each animal for 6 hours. Three inductions were applied at the same site.

control group: Not treated.

Challenge procedure:

day 28 Test group and control group 1:
A 6 hour occluded dermal application of 50% notified polymer in water (0.5 mL) was applied.

Test method: OECD TG 406

Challenge outcome:

Challenge concentration	***Test animals*** 24 hours*	48 hours*	***Control animals*** 24 hours	48 hours
50%	0/17	0/17	0/10	0/10

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

Comment: A positive control group was not included in the study. The test laboratory runs positive tests with α-hexyl-cinnamaldehyde (85%) twice a year.

Three animals in the test group died on day 12, 13 and 15 after application due to pneumonia. Three animals in the test group had scaling after third induction. No erythema or oedema was observed in test animals after inductions.

Rechallenge was not performed in this study.

Result: The notified polymer was non-sensitising to the skin of guinea pigs.

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (Engelhardt, 1994)

Strains: TA1535, TA100, TA1537 and TA98

Metabolic activation: Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.

Concentration range: 0, 20, 100, 500, 2 500 and 5 000 μg/plate with and without S-9 mix (vehicle: aqua dest). Three test plates per dose in both standard plate test and preincubation test.

Positive controls (in DMSO):
(with S-9 mix)
2-aminoanthracene for all strains.

(without S-9 mix)
N-methyl-N’-nitro-N-nitrosoguanidine for TA100 and

TA1535;
4-nitro-o-phenylendiamine for TA98; and
9-aminoacridine chloride monohydrate for TA1537.

Test method: OECD TG 471

Comment: Neither precipitation nor bacteriotoxic effect of the notified polymer was found in the study.

No increase in the number of revertants was observed in the tests with and without S-9 mix.

Result: The notified polymer was non mutagenic under the conditions of the test.

9.3 Overall Assessment of Toxicological Data

The notified polymer was of very low acute oral toxicity (LD_{50}>2 000 mg/kg) and very low acute inhalation toxicity (LC_{50}>5.2 mg/L) in rats. It was not an eye irritant in rabbits or a skin sensitiser in guinea pigs.

The notifier provided two study reports on skin irritation. The first study report showed that the notified polymer was a skin irritant in rabbits, however, in an amendment to the test report, the study director stated that signs of the skin irritation had to be interpreted as artificial as sequela mechanically induced lesion of the superficial layers of the intact skin, because the moistened polymer reportedly has adhesive effects. In the first study, after the polymer was washed from the clipped intact skin, the Draize scores for erythema increased from 1 hour to 24 hours, then remained as moderate irritation to 72 hours and as slight irritation to day 15. In the second study, Miglyol 812N (C8-10 glycerides) was used as the vehicle to avoid the mechanical adhesion effect, and the notified polymer was determined to be a slight skin irritant. Considering the results from the two studies, the notified polymer is considered to be a slight skin irritant.

The notified polymer was non mutagenic under the conditions of an Ames test.

According to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), the notified polymer is not classified as a hazardous substance.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicology data were provided and are not required for polymers of NAMW > 1000. However, anionic polymers containing carboxylate functionalities have been shown to be toxic to green algae (Nabholz *et al*, 1993), with the toxicity apparently due to the ability of the polymer to chelate ions such as calcium, magnesium and iron which the algae require as micronutrients. Subsequently, Boethling and Nabholz (1997) indicate that the toxicity of anionic polymer is greatest when the carboxylate groups are on every alternate carbon of the polymer which is apparently the most favoured steric disposition for chelation by these groups. On the notified polymer, the carboxylate groups are distributed randomly along the chain and the stoichiometry indicates that they could not be attached to every alternate carbon. Consequently, maximum possible toxicity from carboxylate groups is not expected. In harder waters containing higher concentrations of divalent ions (eg. Ca^{2+} and Mg^{2+}), and provided the release of the polymer is not excessive it is expected that sufficient un-chelated metal ions will remain to satisfy the nutrient requirements for algae, so toxic effects would not be apparent.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified polymer is considered to be low when it is used as a component of cosmetic formulations as indicated.

Almost all the introduced polymer will be eventually released into sewers, although this release will be diffuse and Australia-wide. Based on annual imports of 20 tonnes and an Australian population of 19,000,000 each of whom contributes 150 L to the overall sewage volume each day, the global Predicted Environmental Concentration (PEC) in sewage is estimated as a maximum of 20 μg/L. However, once the polymer is released to sewage, the likely high affinity for calcium and magnesium ions in the environment (with formation of neutral insoluble organic salt) indicates that it would associate with the organic component of soils and sediments, and is unlikely to be mobile. Once associated with the sediments the polymer is expected to undergo slow biodegradation to water and carbon dioxide and/or methane. A maximum of 2 tonnes of polymer per year may also be placed into landfill within partially emptied spray cans. When released, it is expected to associate with soils and clay and slowly degrade through biological and abiotic processes.

Little of the polymer is expected to be released to receiving waters and although water soluble/dispersible anionic polymers containing a high proportion of carboxylate groups may exhibit toxicity to green algae through chelation of certain divalent ions such as Ca^{2+} which are required as micronutrients by the algae (Nabholz *et al*, 1993), any toxic effects are expected only in very soft water containing low concentrations of these ions. In harder waters containing higher concentrations of divalent ion, and provided the release of the polymer is not excessive it is expected that sufficient un-chelated metal ions will remain to satisfy the nutrient requirements, so toxic effects would not be apparent (Boethling and Nabholz, 1997). Since divalent calcium and magnesium ions are usually present in most Australian receiving waters in considerable concentration toxic effects against algae from release of the polymer are not expected.

If any material were to reach the general water compartment and remain unassociated with metal ions, the high molecular weight and affinity for water would preclude bioaccumulation. Ultimately the polymer would become associated with metal ions and eventually become assimilated into sediments.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer was of very low acute oral and inhalation toxicity. It was neither an eye irritant nor a skin sensitiser but a slight skin irritant. The notified polymer was not mutagenic in an Ames test. On the available data, the notified polymer is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

The material safety data sheet (MSDS) for Luvimer 100P states that inhalation of the product may result in slight respiratory irritation.

Occupational Health and Safety

There is little potential for significant occupational exposure to the notified polymer in the transport and storage of the polymer and the hair spray products containing the polymer.

The notified polymer is imported in the form of a powder and formulated into hair care products in Australia. The equipment used for formulation and filling of the notified polymer to produce the finished product is enclosed and automated, the occupational exposure to the chemical during these processes is low. However, dermal and/or inhalation exposure may occur during manual operations of weighing and transferring the powder into the mixing tank. Industrial control measures including local exhaust ventilation should be included in the weighing area and in the vicinity of the formulation tanks. Appropriate personal protective equipment such as overalls, protective gloves, safety glasses/chemical goggles and face shield should be worn. A respirator will be required if breathable dust is formed. The MSDS warns not to breath dust. Under these control measures, the risk of adverse health effects resulting from exposure to the polymer at the formulation and packaging sites is expected to be low.

Laboratory workers will be exposed to small quantities of the notified polymer for short periods by dermal contact and inhalation exposure. Exhaust ventilation and personal protective equipment should be available. The risk of adverse health effects resulting from exposure to the polymer for laboratory workers is expected to be low.

Occupational use of the finished products in the hairdressing industry may result in dermal and inhalation exposure to the notified polymer. A higher than normal incidence of respiratory complaints (lung disease and respiratory irritation and asthma) is found among workers in the hairdressing industry. The exact chemical cause cannot be determined in all cases, however the inhalation of aerosol droplets from hair sprays is believed to be a contributing factor (Dahl, 1990; Winder, 1993). Hair dressing industry workers would be expected to have much more frequent exposure than members of the general public using the same formulation. Employers in the hairdressing industry should take precautions to minimise inhalation of spray products, e.g. by providing adequate ventilation for workers and the public. The relevant State or Territory industry guidelines or codes of practice should be observed.

Public Health

Hair care products, including hair spray, will be available to the public and there may be significant public contact with the notified chemical. The toxicity of the notified chemical is low, and the high molecular weight makes it unlikely to cross biological membranes. The use of the notified chemical in hairspray is unlikely to lead to extensive skin contact, and therefore the potential for skin irritation from use of the notified chemical is minimal. The risk to the public from this use of the notified polymer is considered to be negligible.

13. RECOMMENDATIONS

To minimise occupational exposure to Luvimer 100P the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 and AS 3765.2 (Standards Australia, 1990); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/ Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994a); respirators should conform to AS/NZS 1715 (Standards Australia/ Standards New Zealand, 1994b) and AS/NZS 1716 (Standards Australia/ Standards New Zealand, 1994c) and other internationally acceptable standards;

- Employers should ensure that the NOHSC exposure standard for inspirable dust of 10 mg/m^3 is not exceeded in the workplace during formulation;

- Dust masks should be used by formulation workers if local exhaust ventilation is not in place;

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

- A copy of the MSDS should be easily accessible to employees.

- Hairdressers should work in accordance with the relevant State or Territory guidelines or codes of practice;

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), workplace practices and control procedures consistent with State and territory hazardous substances regulations must be in operation.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

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 easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

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