

File No: LTD/1283

May 2007

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

FULL PUBLIC REPORT

VP/Methacrylamide/Vinyl Imidazole Copolymer

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
NICNAS**

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FULL PUBLIC REPORT

VP/Methacrylamide/Vinyl Imidazole Copolymer

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

BASF Australia Ltd (ABN: 62 008 437 867)

500 Princes Highway

Noble Park VIC 3174

NOTIFICATION CATEGORY

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Chemical name; Other names; CAS number; Molecular formula; Molecular weight; Spectral data; Purity; Impurities; Additives/adjuvants; Polymer constituents; Degradation products; Loss of monomers, additives, impurities; Import volume; Use details; Identity of manufacturers/recipients

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

Particle size; Flash point; Flammability Limits; Autoignition temperature; Explosive properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Under assessment in Canada

Luviset Clear can be used as a cosmetic ingredient in EU, USA, China, Korea, Philippines.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

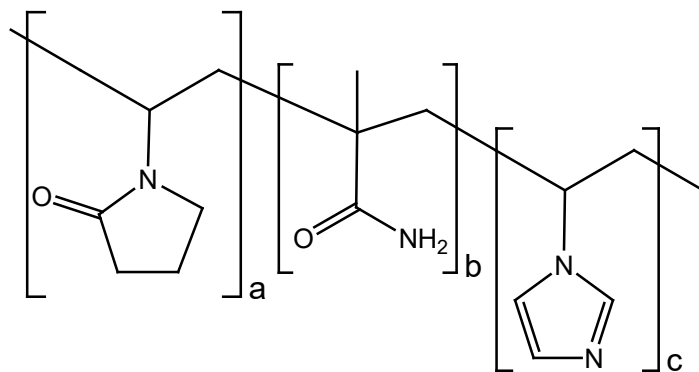
VP/Methacrylamide/Vinyl Imidazole Copolymer (INCI name)

Polymer of N-vinylpyrrolidone, methacrylamide and N-vinyl imidazole

MARKETING NAME(S)

Luviset Clear (19-21% notified polymer in water)

STRUCTURAL FORMULA



METHODS OF DETECTION AND DETERMINATION

METHOD	Infrared spectroscopy
Remarks	The major peaks of the infrared spectrum were consistent with the structure of the notified polymer.
TEST FACILITY	GKA-Analytik (2003)

3. COMPOSITION

DEGREE OF PURITY
>99%

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 a component of Luviset Clear (aqueous solution containing 19-21% notified polymer).

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	1-5	1-5	1-5	1-5	1-5

USE
Film-forming agent for hair styling waxes, gels and mousses.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
BASF Australia Ltd
500 Princes Highway
Noble Park VIC 3174

TRANSPORTATION AND PACKAGING

The notified polymer will be imported by sea in 120 kg net weight plastic (PE) open head drums. It will then be transported by truck to the warehouse for storage until required by the customer. Following reformulation, the final product containing the notified polymer will be packaged into 100 mL, 150 mL, 200 mL and 250 mL plastic tubs/open top jars or squeeze bottles. The containers will then be packed into fibreboard cartons for retail distribution.

5.2. Operation description

Reformulation

Upon arrival at the customer warehouse a sample of the solution containing 19 – 21% of the notified polymer will be obtained for QC testing. Following approval, the aqueous solution will be transferred into a mixing vessel using a sparge and pump from a drum that has been placed on scales. Other components will also be added to the vessel and will be compounded into bulk product in an enclosed system. The concentration of the notified polymer in the finished product will be 0.4 - 1%. Following further quality control testing the approved bulk product will be pumped via automated covered filling lines into individual plastic containers (100 mL - 250 mL).

End uses

The hair styling product containing 0.4 - 1% of the notified polymer will be sold at retail outlets. The

notifier stated that at this stage, sales to the salon market are not anticipated.

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	2-4	2 hours / day	20 days per year
Laboratory/Quality Assurance	2-4	7 hours / day	50 days per year
Plant Operators – Weighing and Compounding	4-6	8 hours / day	50 days per year
Plant Operators – Filling and Packaging	2-4	2 hours / day	20 days per year

Exposure Details

Transport and warehouse workers handling the imported aqueous solution containing up to 21 % notified polymer would only be exposed to the notified polymer in the event of a spill due to an accident or leaking drum.

Dermal and ocular exposure to the notified polymer may occur from drips and spills when pumps are disconnected and connected during reformulation of the notified polymer or dispensing of the final products. Exposure may also occur during quality control sampling and procedures. The maximum concentration to which workers may be exposed during such procedures will be < 21% and may be as low as $\leq 1\%$.

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

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Melbourne, and stored at a contracted warehouse. It will be transported by road to Sydney where it will be formulated with other ingredients to produce hair care products (typically hair styling waxes, gels and mousses). 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. It is expected that up to 0.5% of total imported notified polymer will remain in these containers, which will be sent to drum reconditioners. Emptied drums will probably follow lifecycle processes (e.g. cleaning and washing, reconditioning and re-use). Drum reconditioning and cleaning wastewaters are likely to be released to on-site wastewater treatment plants and/or the sewer.

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 to trade waste system and biological processing treatment plant. Once treated, the wastewater is disposed 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.

RELEASE OF CHEMICAL FROM USE

The end-use products containing the notified polymer are applied to hair as a styling agent. Due to the properties of the notified polymer, it 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 via domestic waste to landfill, the majority of the 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 majority of the notified polymer will ultimately be disposed of in either the sewer (major) or

through domestic waste to landfill. In the aquatic environment, the notified polymer is expected to eventually degrade to form various simple organic and nitrogen based compounds.

5.6. Public exposure

There will be widespread and repeated exposure of the public to the notified polymer, which is a component of hair care styling products. Members of the public will dispense the notified polymer from open top jars or squeeze bottles into the fingers and then massage through the hair. The notified polymer does not bond permanently to the hair and will be washed off during routine hair washing. Dermal and ocular exposure, as well as possible ingestion of the notified polymer may occur. However, the notified polymer is present at relatively low levels (0.4 – 1%).

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Clear, colourless, crystalline powder

Melting Point > 400 °C

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks DSC method. The test substance showed no reproducible melting point between 0 °C and 400 °C.
TEST FACILITY BASF (2007)

Boiling Point Not determined

Remarks The normal boiling point could not be determined because the vapour pressure is very low.
TEST FACILITY BASF (2007)

Density 1141 kg/m³ at 20°C

METHOD OECD TG 109 Density of Liquids and Solids, pycnometer method
TEST FACILITY BASF (2007)

Vapour Pressure < 10⁻⁷ kPa at 20°C and at 50°C

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Effusion method. The vapour pressure was below the detection limit.
TEST FACILITY BASF (2007)

Water Solubility ≥504 g/L at 23°C (Estimate)

METHOD BASF SOP PCE/006
Remarks Due to the high miscibility of the test item in water, it was not possible to apply the common methods for the determination of water solubility. Therefore, the miscibility of the test item in water was assessed visually. Measuring the pH values of the aqueous preparations was not possible, nor considered sensible, because of their very high viscosity.
TEST FACILITY BASF (2007)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

pH	T (°C)	t _{1/2} <hours or days>
4	50	Nil hydrolysis observed.
7	50	Nil hydrolysis observed.

Remarks	The ¹ H-NMR signals of the test item show no significant changes in the test solutions during the test and no formation of degradation products were found during the tests. Also the ¹ H-NMR spectra of the test solutions of the hydrolysis tests show no significant differences to the ¹ H-NMR spectra of the test item dissolved in D ₂ O, measured during the characterization study. Thus it can be stated that the test item is hydrolytic stable.
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TEST FACILITY	BASF (2007)
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Partition Coefficient (n-octanol/water) log Pow < -4.6 at 20°C

METHOD	Estimation
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Remarks	Neither the shake/flask method nor the HPLC method were appropriate, and as the water solubility is very high, but not determinable exactly, the log P _{OW} can only be estimated from the single solubilities of the test substance in water and 1-octanol, respectively.
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TEST FACILITY	11.56 mg of test substance was dissolved in 1000 mL of 1-octanol. After stirring over night at 23°C the test item was not dissolved, as the test item was visible as white sediment. Using the water solubility determined above, the P _{OW} was determined to be <0.000024. BASF (2007)
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Adsorption/Desorption Not determined

Remarks	As the test substance cannot be analysed by HPLC, it is not possible to determine the log K _{OC} according to the OECD Guideline 121.
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TEST FACILITY	BASF (2007)
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Dissociation Constant Not determined

METHOD	OECD TG 112 Dissociation Constants in Water.
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Remarks	The high molecular weight of the test item, with a great number of basic centres in one molecule, leads theoretically to several dissociation constants that lie close together. Therefore, a single dissociation constant could not be calculated.
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TEST FACILITY	BASF (2007)
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Particle Size Not determined

Remarks	The notified polymer cannot be isolated from water, and is imported into Australia as an aqueous solution.
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Flash Point Not determined

Remarks	The low vapour pressure of the notified polymer indicates that it is likely to have a high flash point.
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Flammability Limits Not determined

Remarks	The notified polymer is not expected to be flammable.
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Autoignition Temperature Not determined

Remarks	The notified polymer is not expected to auto-ignite under normal conditions of use.
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Explosive Properties Not predicted to be explosive.

Remarks	Test not conducted. From examination of the structure, there are no chemical
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groups that would infer explosive properties.

Reactivity

Not determined

Remarks

The notified polymer is expected to be stable under normal conditions of use.

7. TOXICOLOGICAL INVESTIGATIONS

All tests were conducted using Luviset Clear containing 24.3% of the notified polymer.

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 >2000 mg/kg bw	Low toxicity
Rabbit, skin irritation	Moderately irritating
Rabbit, eye irritation	Non-irritating
Genotoxicity - bacterial reverse mutation	Non-mutagenic
Mouse, skin sensitisation – LLNA	No evidence of sensitisation

7.1. Acute toxicity – oral

TEST SUBSTANCE	Luviset Clear
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 96/54/EC B.1.tris Acute Toxicity (Oral) – Acute Toxic Class Method
Species/Strain	Rat/Wistar/CrlGlxBrlHan:WI
Vehicle	Doubly distilled water
Remarks - Method	No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3F	2000	0
2	3F	2000	0

LD50	>2000 mg/kg bw test substance
Signs of Toxicity	No signs of toxicity
Effects in Organs	No abnormal clinical observations were made.
Remarks - Results	Under the conditions of this study, the median lethal dose of the test substance (Luviset Clear) after oral administration was found to be greater than 2000 mg/kg body weight in rats, equivalent to > 486 mg/kg body weight for the notified polymer.

CONCLUSION	Luviset Clear is of low toxicity via the oral route. The notified polymer is likely to be of low toxicity.
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TEST FACILITY	BASF (2003a)
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7.2. Irritation – skin

TEST SUBSTANCE	Luviset Clear
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White/A1077 INRA (SPF)
Number of Animals	3 (2M, 1F)
Vehicle	None

Observation Period 14 days
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations.

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>	1.3	1.7	2.0	3	< 15 days	0
<i>Oedema</i>	0	0.3	0.3	1	< 48 hr	0

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

Remarks - Results Moderate erythema (grade 2) was observed in all animals immediately, and one hour after removal of the patch. This persisted in 2 animals up to the 24 hour observation and increased to marked (grade 3) in the third animal at the 24 hour observation.
At the 48 hour observation, the marked erythema decreased to moderate, and one of the two moderate erythema decreased to slight, while another one stayed as moderate.
Slight erythema was observed in all animals at the 72 hour observation. Erythema were reversible in two animals within 7 days and in one animal within 15 days after patch removal.
Slight edema was noted in all animals 1 hour after patch removal, and persisted in two of the animals up to the 24-hour time point.
Mechanical skin lesions due to adhesive properties of the test substance were noted in all animals during the observation period, and remaining in two of the animals at study termination at day 7.
The investigators concluded that the observed skin reactions are likely to be a secondary effect related to the mechanical adhesion of the test substance.

CONCLUSION Luviset Clear is moderately irritating to the skin.

TEST FACILITY BASF (2003b)

7.3. Irritation – eye

TEST SUBSTANCE Luviset Clear

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White/A1077 INRA (SPF)
Number of Animals 3 (2F, 1M)
Observation Period 72 hr
Remarks - Method No significant protocol deviations

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	0	0	1	< 24 hr	0
<i>Conjunctiva: chemosis</i>	0	0	0	0	0	0
<i>Conjunctiva: discharge</i>	0	0	0	0	0	0
<i>Corneal opacity</i>	0	0	0	0	0	0
<i>Iridial inflammation</i>	0	0	0	0	0	0

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

Remarks - Results	Slight conjunctival redness was noted in one animal 1 hour after application. No other ocular reactions were observed during the study.
CONCLUSION	Luviset Clear is non-irritating to the eye.
TEST FACILITY	BASF (2003c)

7.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Luviset Clear
METHOD	OECD 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/CBA/CaOlaHsd
Vehicle	Propylene glycol
Remarks - Method	A concurrent positive control with a known sensitiser was not included in this study. Studies using Alpha-Hexylcinnamaldehyde techn. 85% are performed in the laboratory twice a year and the results of one such test are shown below. Radiolabelling was not used to determine the cell count. Lymph node response was evaluated by measuring the lymph node weight, lymph node cell count, and the weight of a circular piece of tissue (0.8cm diameter) taken from the apical part of the ear.

RESULTS

<i>Concentration (% w/w)</i>	<i>Proliferative response (Counts/lymph node pair)</i>	<i>Stimulation Index (Test/Control Ratio)</i>
<i>Test Substance</i>		
0 (vehicle control)	7,968,333	1.00
10%	5,905,500	0.74
30%	6,201,833	0.78
Undiluted	10,027,000	1.26
<i>Positive Control*</i>		
Vehicle (acetone)		1.00
3%		1.78
10%		2.01
30%		2.28

*Alpha-Hexylcinnamaldehyde techn. 85%

Remarks - Results	No signs of systemic toxicity were observed. The investigators note that the slight increase in ear weights when applied undiluted indicates some irritation of the ear skin and demonstrates the achievement of skin irritation effect concentration. The statistically significant increase in lymph node weights induced by the undiluted test substance is considered to be caused by the inflammatory event in the ear skin. Cell counts were not statistically significantly increased at all concentrations.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to Luviset Clear.
TEST FACILITY	BASF (2003d)

7.5. Genotoxicity – bacteria

TEST SUBSTANCE	Luviset Clear
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test

Species/Strain	using Bacteria. Plate incorporation procedure and Pre incubation procedure <i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 80-20,000 µg/plate b) Without metabolic activation: 80-20,000 µg/plate
Vehicle	Water
Remarks - Method	2-Aminoanthracene was used as the only indicator of the efficacy of the S9-mix.

The positive controls used for TA 98, TA 100, and TA 1535 were not those recommended by the test method, however, the investigators have stated that the selected positive controls are stable under the culture conditions used, since they are well-established reference mutagens.

The highest concentration tested was 20,000 µg/plate.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test 1	>20,000	>20,000	>20,000	Negative
Test 2	>20,000	>20,000	>20,000	Negative
<i>Present</i>				
Test 1	>20,000	>20,000	>20,000	Negative
Test 2	>20,000	>20,000	>20,000	Negative

Remarks - Results	No toxicity or precipitation was observed. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of metabolic activation. Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system.
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CONCLUSION	Luviset Clear was not mutagenic to bacteria under the conditions of the test.
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TEST FACILITY	BASF (2003e)
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8. ENVIRONMENT

All tests outlined in this section were conducted using Luviset Clear containing 24.3% of the notified polymer.

8.1. Environmental fate

8.1.1. Inherent biodegradability

TEST SUBSTANCE	Luviset Clear
METHOD	OECD TG 302 B Determination of the Biodegradability in the Static Test (Zahn Wellens Method)
Inoculum	Sewage sludge from a laboratory municipal wastewater treatment plant.
Exposure Period	28 Days
Auxiliary Solvent	None
Analytical Monitoring	Unspecified Organic Carbon analysis.
Remarks - Method	Duplicate samples of approximately 1450 mg/L test substance containing dissolved organic carbon (DOC) equivalent to 200 mg/L were exposed to

sewage sludge micro-organisms. A blank control and reference substance (ethylene glycol) were also run. An abiotic control containing the test substance and inoculum, but poisoned with 10 g/L at the initiation of the test and 15 g/L at day 14, was run.
 Temperature: 22.5±0.5°C
 pH: 6.4-7.7

RESULTS

<i>Test substance</i>		<i>Ethylene glycol</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
1	7	1	10
7	10	7	99
10	10	10	99
14	12	14	100
28	15	28	101

Remarks - Results	The abiotic control showed less than 10% degradation, demonstrating that the degradation was not due to abiotic means. The reference substance showed acceptable degradation with 90-100% in 14 days. A correction was made for three hours until the initiation of the test when the first DOC concentration value was measured.
CONCLUSION	The notified polymer is not inherently biodegradable and is poorly eliminable from water.
TEST FACILITY	BASF (2003f)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Luviset Clear
METHOD	In accordance with OECD TG 203 Fish, Acute Toxicity Test and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish -static.
Species	Zebra fish (<i>Danio rerio</i>)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	~ 250 mg CaCO ₃ /L
Analytical Monitoring	Visual, Pyrolysis gas chromatography
Remarks – Method	Ten fish were exposed to a nominal concentration of 100 mg/L test substance and a control. Temperature 24°C pH 7.5-8.5 Light: 16 hours light; 8 hours dark; 82-280 Lux.

RESULTS

Concentration mg/L		Number of Fish	Mortality				
Nominal	Actual		1 h	24 h	48 h	72 h	96 h
Control	-	10	0	0	0	0	0
100	109	10	0	0	0	0	0

LC50	≥109 mg/L at 96 hours for the test substance; and ≥26.5 mg/L at 96 hours for the notified polymer.
NOEC	109 mg/L at 96 hours for the test substance; and 26.5 mg/L at 96 hours for the notified polymer.
Remarks – Results	No abnormal behaviour was observed in any fish.

CONCLUSION	The notified polymer is, at most, harmful to fish.
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TEST FACILITY	BASF (2003g)
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8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Luviset Clear
METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test and Reproduction Test - Static.
Species	<i>Daphnia magna</i> Straus
Exposure Period	48 hours
Auxiliary Solvent	None indicated
Water Hardness	~245 mg CaCO ₃ /L
Analytical Monitoring	Visual; Pyrolysis gas chromatography.
Remarks - Method	Four replicates of five daphnids were exposed to nominal concentrations of test substance detailed below and a control. Temperature: 19.8-20.4°C Oxygen 8.2-8.8 mg O ₂ /L pH: 8.1-8.2

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
0		20	0	0
12.5		20	0	0
25		20	0	0
50		20	0	0
100		20	0	0

LC50	≥100 mg/L at 48 hours for the test substance; and ≥24.8 mg/L at 48 hours for the notified chemical.
NOEC	100 mg/L at 48 hours for the test substance; and 24.8 mg/L at 48 hours for the notified chemical.
Remarks - Results	The recovery of the highest concentration was 104% at the commencement of the test and 107% at its completion. The EC50 (24h) of a reference substance (potassium dichromate) run 4 months prior to this test was 1.33 mg/L.

CONCLUSION	The notified polymer is, at most, harmful to daphnia
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TEST FACILITY	BASF (2003h)
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8.2.3. Inhibition of microbial activity

TEST SUBSTANCE	Luviset Clear
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.
Inoculum	Activated sludge from laboratory wastewater plant treating municipal sewage.
Exposure Period	0.5 hours
Concentration Range	Nominal: 1000 mg/L
Remarks – Method	Triplicate samples of activated sludge were subjected to a nominal concentration of 1000 mg/L of test substance. A control and reference substance (3,5-dichlorophenol) were also run.
RESULTS	
IC50	≥1000 mg/L for the test substance; and ≥243mg/L for the notified chemical.
NOEC	1000 mg/L for the test substance; and 243mg/L for the notified chemical.
Remarks – Results	The test substance showed a slight increase in oxygen consumption rate, The EC50 reference substance was ~15 mg/L, which was within the accepted range of 5-30 mg/L.
CONCLUSION	The notified polymer is not inhibitory to sludge micro-organisms.
TEST FACILITY	BASF (2003i)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Since most of the polymer will be washed into the sewer, under a worst case scenario, with no removal of the notified polymer in the sewage treatment plant, the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

PEC for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	5,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	13.70	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	3.34	µg/L
PEC - Ocean:	0.33	µg/L

9.1.2. Environment – effects assessment

Based on the lowest result of the two ecotoxicity studies provided, the Predicted No Effect Concentration (PNEC) has been calculated as follows:

PNEC for the Aquatic Compartment	
EC50 (Invertebrates)	24.80 mg/L

Assessment Factor	1,000
PNEC:	24.80 $\mu\text{g/L}$

9.1.3. Environment – risk characterisation

Using the PEC and PNEC calculated above, the Risk Quotient (RQ) has been calculated as follows:

Risk Assessment	PEC $\mu\text{g/L}$	PNEC $\mu\text{g/L}$	Q
RQ - River:	3.34	24.8	0.135
RQ - Ocean:	0.33	24.8	0.013

As the RQ is below 1, the proposed use pattern of the notified polymer is not expected to pose an unacceptable risk to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Dermal and occasional ocular exposure to the notified polymer (concentrations up to 21%) may occur during QC testing, when opening and closing drums, and when connecting and disconnecting pumps. Mixing vessels are enclosed and workers are provided with personal protective equipment for use during reformulation operations.

Exposure during filling and packaging operations is likely to be minimal, due to the use of automated covered filling lines. The maximum level of worker exposure to the notified polymer would be $\leq 1\%$.

9.2.2. Public health – exposure assessment

Exposure will be principally by the dermal route, particularly due to the leave-on nature of the hair products, with the potential for occasional accidental ocular exposure or ingestion.

9.2.3. Human health – effects assessment

Luviset Clear was of low acute oral toxicity in rats ($\text{LD}_{50} > 2000 \text{ mg/kg bw}$). It could not be determined whether the notified polymer is also of low toxicity.

Luviset Clear was found to be moderately irritating to the skin, however, the severity of the irritation does not meet the NOHSC *Approved Criteria for Classifying Hazardous Substances*. It was not irritating to the eyes of rabbits. There was no evidence of skin sensitisation and it was found to be non-mutagenic. The notified polymer may have similar properties, however, this could not be conclusively determined based on the toxicity tests provided.

Based on the available data on the tested material, the notified polymer at 24.3% concentration is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The data provided suggest that the notified polymer may be of low acute oral toxicity, and was not an eye irritant or skin sensitiser. It has the potential to cause moderate skin irritation at its imported concentrations of $\leq 21\%$. However, reformulation processes are largely automated and enclosed and workers use personal protective equipment so that the risk of adverse health effects would be limited to drips and spills associated with transfer operations. Given the chemical nature of the polymer ($\text{NAMW} > 10,000$ and low level of low molecular weight species), absorption across biological membranes is not expected. The risk of adverse health effects can be considered to be low.

9.2.5. Public health – risk characterisation

The data available on the health effects of the notified polymer indicate a low hazard. The public will be exposed to the notified polymer on the scalp at concentrations of 0.4 - 1%. At such low concentrations, there is negligible likelihood of systemic effects and a low likelihood of irritant or sensitising effects, even on repeated or prolonged exposure. In addition, the notified polymer is not expected to be absorbed due to its high molecular weight ($> 10,000$) and

low levels of low molecular weight species. Therefore the risk to public health from use of products containing the notified polymer is considered to be low.

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 the 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 classification of the notified polymer is based on testing performed on an aqueous solution of the notified polymer (24.3%), containing low levels of impurities present at concentrations significantly below the cut off for irritation classification.

	<i>Hazard category</i>	<i>Hazard statement</i>
Mild irritant	3	Causes mild skin irritation

10.2. Environmental risk assessment

On the basis of the PEC/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 No Significant Concern to public health when used in the manner described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of products containing 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 products containing 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 engineering controls to minimise occupational exposure to the imported notified polymer:

- Reformulation operations should be performed in well-ventilated areas.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid contact with skin.
 - Prevent overfilling of containers.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Gloves, safety glasses, safety boots, coveralls/laboratory coats.

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 chemical 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.

Environment

- The notified polymer should be disposed of to landfill.
- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

12.1. Secondary notification

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

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000
 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.

No additional secondary notification conditions are stipulated.

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