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

**FULL PUBLIC REPORT**

**Collacral VAL**

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 9577 8888.
Website:	<a href="http://www.nicnas.gov.au">www.nicnas.gov.au</a>

**Director  
Chemicals Notification and Assessment**

## **TABLE OF CONTENTS**

FULL PUBLIC REPORT .....	3
1. APPLICANT AND NOTIFICATION DETAILS .....	3
2. IDENTITY OF CHEMICAL .....	3
3. COMPOSITION.....	4
4. INTRODUCTION AND USE INFORMATION.....	4
5. PROCESS AND RELEASE INFORMATION.....	4
5.1. Distribution, Transport and Storage.....	4
5.2. Operation Description.....	4
5.3. Occupational exposure.....	5
5.4. Release.....	5
5.5. Disposal .....	6
5.6. Public exposure.....	6
6. PHYSICAL AND CHEMICAL PROPERTIES.....	6
7. TOXICOLOGICAL INVESTIGATIONS .....	9
7.1. Acute toxicity – oral .....	9
7.2. Acute toxicity - dermal .....	9
7.3. Acute toxicity - inhalation .....	10
7.4. Irritation – skin .....	10
7.5. Irritation - eye .....	10
7.6. Skin sensitisation .....	11
7.7. Repeat dose toxicity.....	11
7.8. Genotoxicity - bacteria.....	12
7.9. Genotoxicity – in vitro.....	12
7.10. Genotoxicity – in vivo .....	12
8. ENVIRONMENT.....	12
8.1. Environmental fate.....	12
8.1.1. Ultimate biodegradability .....	12
8.1.2. Bioaccumulation .....	13
8.2. Ecotoxicological investigations .....	13
8.2.1. Acute toxicity to fish.....	13
8.2.3. Algal growth inhibition test .....	14
8.2.4. Inhibition of microbial activity .....	15
9. RISK ASSESSMENT .....	15
9.1. Environment .....	15
9.1.1. Environment – exposure assessment.....	15
9.1.2. Environment – effects assessment .....	16
9.1.3. Environment – risk characterisation.....	16
9.2. Human health.....	16
9.2.1. Occupational health and safety – exposure assessment .....	16
9.2.2. Public health – exposure assessment.....	16
9.2.3. Human health - effects assessment .....	17
9.2.4. Occupational health and safety – risk characterisation .....	17
9.2.5. Public health – risk characterisation.....	17
10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS .....	17
10.1. Hazard classification.....	17
10.2. Environmental risk assessment .....	17
10.3. Human health risk assessment .....	17
10.3.1. Occupational health and safety.....	17
10.3.2. Public health.....	18
11. MATERIAL SAFETY DATA SHEET .....	18
11.1. Material Safety Data Sheet .....	18
11.2. Label .....	18
12. RECOMMENDATIONS.....	18
12.1. Secondary notification .....	18
13. BIBLIOGRAPHY .....	19

**FULL PUBLIC REPORT****Collacral VAL****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT

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

## NOTIFICATION CATEGORY

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

## EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical name

Other names

CAS number

Molecular formula

Structural formula

Spectral data

Polymer ingredients and weight %

Number average molecular weight

Residual monomers and other reactants

Low molecular weight polymer

Degradation products

Loss of monomers, additives, impurities

## VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

Acute dermal toxicity

Acute inhalation toxicity

Repeated dose toxicity

Induction of germ cell damage

Chromosome damage.

Analogue toxicity data has been submitted in the form of a CIR assessment of data on a close analogue polymer.

## PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Commercial Evaluation Permit No. 503, February 2002

## NOTIFICATION IN OTHER COUNTRIES

USA

Korea

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

Collacral VAL

## METHODS OF DETECTION AND DETERMINATION

ANALYTICAL      Infrared spectroscopy  
METHOD

Remarks A reference spectrum was provided by the notifier.

### 3. COMPOSITION

DEGREE OF PURITY  
> 99 %

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

<i>Chemical Name</i>	2-propanol		
<i>CAS No.</i>	67-63-0	<i>Weight %</i>	0.05
<i>Hazardous Properties</i>	NOHSC exposure standard 400 ppm TWA, 500 ppm STEL (NOHSC, 1995)		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)  
None

ADDITIVES/ADJUVANTS

<i>Chemical Name</i>	water		
<i>CAS No.</i>	7732-18-5	<i>Weight %</i>	70

### 4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia; it will be imported as a 30 % aqueous solution and reformulated in Australia.

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

The notified polymer will be imported in a quantity in the range of 1 to 10 tonnes per annum.

USE

The notified polymer will be used as a thickener and stabiliser for polymer dispersions and other aqueous systems for waterproofing membrane formulations.

### 5. PROCESS AND RELEASE INFORMATION

#### 5.1. Distribution, Transport and Storage

PORT OF ENTRY  
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS  
Carson Adhesives (NSW)  
Parbury Technologies (VIC)

TRANSPORTATION AND PACKAGING

The notified polymer will be imported by sea and transported to warehouses and customer sites by road. The 30 % aqueous solution will be packaged in 120 kg plastic drums.

#### 5.2. Operation Description

The notified polymer will be imported as a 30 % aqueous solution and reformulated at two customer sites to produce an aqueous dispersion used for a waterproofing membrane formulation. The notified polymer will be used at approximately 9 – 12 kg per 6 tonne batch in a styrene-acrylic aqueous dispersion, which also contains fillers such as calcium carbonate, and wetting agents. This equates to a final concentration of notified polymer of 0.15 – 0.2 % in the dispersion. The concentration may range up to 2 %. Up to 5 batches will be produced per week. The finished product will be packaged in 20 kg, 10 kg or 4 kg plastic pails. The end-use product will be sold to tradespeople and applied by

brush or roller to concrete or fibre cement substrates. After the film has dried, the notified polymer is expected to be bound within the film.

### 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 Storage	6 - 8	30 minutes per day	daily
Labourers	8	30 minutes per day	daily
Laboratory Technicians	8	30 minutes per day	daily
Waterproofing Tradespeople	50 - 100	8 hours per day	daily

#### *Exposure Details*

Transport and storage workers will only handle the notified polymer solution in sealed containers, and no exposure is expected except in the case of an accident involving damage to the containers.

Labourers will scoop the 30 % notified polymer solution from the imported containers using a pail or jug, and add the solution to mixing vessels, where it is diluted to a maximum concentration of 2 %. Dermal exposure to the 30 % solution may occur during this process. After blending, the labourers will drain the end-use product from the production vessel into the containers for trade sale. Laboratory technicians will be responsible for sampling the blended product and running quality assurance tests. During these processes, there may be dermal exposure to the product containing a maximum of 2 % notified polymer.

Tradespeople will apply the waterproofing formulation to a variety of substrates at job sites throughout Australia. Application will be by brush or roller to a variety of substrates such as concrete or fibre cement. Accidental dermal or ocular exposure is probable during application of the formulation, which contains a maximum of 2 % notified polymer.

Local exhaust ventilation will be used where natural ventilation is inadequate; in addition, the notified polymer has low volatility and the polymer solution and finished products are viscous, reducing the likelihood of aerosol formation or splashing. Labourers will wear coveralls, chemical goggles or safety glasses, boots, face shield, aprons and impervious gloves, while laboratory technicians are expected to wear laboratory coats and safety glasses. Controls used to minimise exposure for application tradespeople have not been specified by the notifier.

### 5.4. Release

#### RELEASE OF CHEMICAL AT SITE

Release of the notified polymer to the environment at customer facilities could occur through cleaning and washing of mixing vessels, and from incidental spills during normal operational procedures. Small incidental spills and material washed from mixing vessels will be flushed away for effluent treatment in each of the factory's effluent treatment systems. The notifier expects that < 10 kg of polymer will be discharged to the effluent treatment facilities each year from small spills (approximately 200 g per week). In addition, the notifier estimates that less than 1 % of the total formulated product will be discharged to waste water streams for treatment as a result of vessel cleaning. The notifier estimated that a maximum of 5 batches (6 tonnes per batch) of the formulated product, equating to 30000 kg, will be produced per week. If it is assumed that 1 % of the formulated product is lost during vessel washing, then about 600 g per week of the notified polymer (0.2 % of the end product) will be released during vessel washing. Therefore, release of the notified polymer to on-site effluent treatment facilities as a result of spills and vessel washing combined will be approximately 800 g per week.

The notifier estimates 1 % of the final waterproofing product will remain in the 20, 10 and 4 L plastic pails when they are finally discarded. Assuming the entire 10 tonnes of the new polymer imported each year is used to manufacture the final waterproofing product, then a maximum of 100 kg per year of notified polymer in container residues may be discarded in landfill.

#### RELEASE OF CHEMICAL FROM USE

Release during application of the final waterproofing product would occur via domestic sewer systems anywhere in Australia where the product is used. The notifier estimates that between 50 and 100 trades people will use the formulated product on a daily basis, and that approximately 100 - 200 g of the formulated product will be washed from the application brush per tradesman each day. This means that a total of 20 kg of the formulated product will be washed off into domestic sewer each day, indicating that a total of 40 g of the new polymer per day will enter waterways via this route. Release

into the environment from the end use waterproofing paint film is not expected once the product dries, though some release from roofs to stormwater may occur if rain occurs shortly after application.

### 5.5. Disposal

Small incidental spills and waste produced during normal operations may be washed into the on-site effluent treatment facilities. The solids separated from the wastewater will be disposed of in properly labelled drums to approved landfill sites. Larger spills will be contained and soaked up with absorbent materials before being transported off-site to an approved industrial facility for disposal by incineration or will be sent to landfill (estimated 40 kg per annum). The most likely route of disposal of container residues will be via a dumpster bin or industrial skip to landfill.

### 5.6. Public exposure

There is potential for public exposure to the notified polymer in an accidental spillage during transportation. In the event of spillage, the spill should be prevented from entering drains or water sources. The spill (< 40 kg/year of the notified polymer) should be soaked up with absorbent material before being transported off-site to an approved industrial facility for disposal by incineration or landfill by approved operators. Small spills (< 10 kg/year of the notified polymer) will be flushed away for effluent treatment plant. During the reformulation, waste washings from the mixing vessel (<1 % or 60 kg/year of the notified polymer) are properly treated in an effluent treatment plant before discharge. Solids separated at the wastewater treatment plant are disposed in properly labelled drums to approved landfill sites. Brush washing during application will enter the soil or waterways. Dried residue in empty pails which is estimated to be maximally 1 % (10-100 kg/year of the notified polymer) will be discharged to landfill.

The end-use product containing < 2 % of the notified polymer will be applied to concrete or fibre cement to form a waterproofing membrane. Once dried, the product becomes a paint film and the notified polymer is no longer bioavailable. Hence, minimal public exposure and health hazard will be expected.

## 6. PHYSICAL AND CHEMICAL PROPERTIES

No test reports for some physical and chemical properties have been provided. In many cases, the physico-chemical data is for the 30 % aqueous solution of the notified polymer.

<b>Appearance at 20°C and 101.3 kPa</b>		Yellowish to cloudy liquid with faint odour.
<b>Freezing Point</b>		0°C
Remarks	Aqueous solution.	
<b>Boiling Point</b>		100°C at 101.3 kPa
Remarks	Aqueous solution.	
<b>Density</b>		1050 kg/m <sup>3</sup> at 20°C
Remarks	Aqueous solution.	
<b>Vapour Pressure</b>		3.0 kPa at 20°C
Remarks	Aqueous solution.	
<b>Water Solubility</b>		Miscible
METHOD	EC Directive 92/69/EEC, A.6, flask method	
Remarks	A pre-test for water solubility was carried out at buffer pH 7, in which 10 mL of buffer = 7 was added to 224 mg of test item, and the amount of test item incrementally increased up to 1164 mg. The substance was observed to foam a little, however, no solids were observed. When a light was shone upon the solution, the test item appeared to be colloidal dissolved. Following the pre-test, a	

definitive water solubility test was performed with 3 buffer pH values (1, 7, and 10) and with ratios of test item to buffer solution varying from 1:1, 9:1 and 1:9. During the test, the required amounts of test substance, beginning with 15 g, was added to the buffer solutions and stirred at 30°C for 24, 48 and 72 hours respectively. The solutions were then left to stand for 24 h at 20°C. The test media was then centrifuged, and the carbon content in each fraction analysed. All solutions were observed to have a muddy appearance after centrifugation. Test results showed the polymer to be colloidal miscible in water at all test concentrations and pH conditions.

TEST FACILITY BASF Aktiengesellschaft ZAX Analytik (2001a)

#### n-Octanol Solubility

< 6 g/100 g at 20°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.

Remarks Analytical Method: Nitrogen content determined by Kjeldahl method.

A definitive test was carried using about 2 g of test material mixed with about 20-25 g of octanol. The mixtures were shaken and stirred for from 3 to 24 hours and allowed to stand for 1 hour. After centrifuging, the samples were analysed for their nitrogen content. The solubility of the notified polymer in octanol was found to be between 13 and 56 g/L. The tested polymer contains 70 % water, which does not dissolve in octanol, therefore the content of the copolymer found in octanol resulted from the 30 % of the test item comprising the copolymer. These result indicate the notified polymer has an affinity for lipids.

TEST FACILITY BASF Aktiengesellschaft ZAX Analytik (2001a)

#### Hydrolysis as a Function of pH

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

<i>pH</i>	<i>T (°C)</i>	<i>t<sub>1/2</sub> hours</i>
4	50, 70, 80	270, 69, 50
7	50, 70, 80	161, 64, 26
9		No reaction observed

Remarks A direct hydrolysis test was performed at buffer pH 4.0, 7.0 and 9, and at temperatures of 50, 70 and 80°C using 8 and 80 g test substance in 500 mL buffer solution. After heating the solutions to the required temperatures, 5 mL aliquots of the sample solutions were removed for analyses using Capillary Gas Chromatography. However, direct hydrolyses of the test substance could not be determined because gas chromatography failed to detect any test material. Thus no half-lives for Collacral VAL are available. The test material hydrolysed to form acetic acid and versatic acid. Therefore the values in the table refer to the formation of acetic acid. The maximum amount of acetic acid that could form from 100 g of Collacral VAL is 7.8 g. However, the measured values for acetic acid formation were significantly lower than this.

TEST FACILITY BASF Aktiengesellschaft ZAX Analytik (2001b)

#### Surface Tension

39.7 mN/m at 20°C

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.

EC Directive 92/69/EEC A.5 Surface Tension.

Remarks Concentration: 1 g/L

#### Viscosity

100 s at 23°C

METHOD DIN 53785

Remarks Approximately 20 % aqueous solution.

**Partition Coefficient (n-octanol/water)** Not determined

METHOD	OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.
Remarks	A pre-test was performed using freeze-dried test item, where 0.41 g of test item was mixed with 10 mL of octanol at 37°C. After standing for a day, the test item was deposited at the bottom of the test vessel, and the supernatant appeared a little muddy. The partition coefficient could not be determined as the substance was found to be surface active.
TEST FACILITY	BASF Aktiengesellschaft ZAX Analytik (2001a).

**Adsorption/Desorption** Not determined

METHOD	OECD TG 106 Adsorption - Desorption.
Remarks	An attempt was made to measure the adsorption coefficient using the HPLC screening method. No peaks could be observed on the chromatogram during the test. The notified polymer is colloidal miscible in water and hence could have some mobility in soil environments. However, the polymer also has an affinity to lipids and therefore would be expected to adsorb to organic matter and remain immobile in soils.
TEST FACILITY	BASF Aktiengesellschaft ZAX Analytik (2001b)

**Dissociation Constant** Not determined.

Remarks	The molecule does not contain any acidic groups. The notified polymer is expected to have basicity comparable to acetamide which has a $pK_b=14.5$ .
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**Particle Size** Not determined

Remarks	The notified polymer will only be present in Australia in solution form.
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**Flash Point** None detected

METHOD	DIN 51758
Remarks	Aqueous solution is not expected to be flammable.

**Flammability Limits** Not flammable

Remarks	Aqueous solution is not expected to be flammable.
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**Autoignition Temperature** None detected

METHOD	DIN 51794
Remarks	Aqueous solution is not expected to be flammable.

**Explosive Properties**

Remarks	Not expected to be explosive, based on structure.
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**Reactivity**

Remarks	Expected to be stable under normal environmental conditions.
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## 7. TOXICOLOGICAL INVESTIGATIONS

Analogue toxicity data has been provided for some of the endpoints for which studies on the notified polymer are not available. As the analogue data is in the form of a review, it is not clear what the molecular weight range of the analogue used for any of the studies is, but the chemical constitution of the analogue is close to that of the notified polymer.



<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal	not determined
Rat, acute inhalation	not determined
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test/non-adjuvant test.	no evidence of sensitisation.
Rat, repeat dose toxicity	not determined
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro	not determined
Genotoxicity – in vivo	not determined

### 7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (as a 30.2 % aqueous solution)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar (SPF) CrI:WI(GLX/BRL/HAN)IGS BR
Vehicle	Distilled water; dose volume 10mL/kg
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>
I	3 per sex	2000	0/6

LD50	> 2000 mg/kg bw
Signs of Toxicity	No clinical signs of toxicity were observed.
Effects in Organs	No gross abnormalities were seen at necropsy.
Remarks - Results	The animals gained weight through the study.

CONCLUSION The notified polymer is of low toxicity via the oral route.

TEST FACILITY BASF Aktiengesellschaft Experimental Toxicology and Ecology (2000a)

### 7.2. Acute toxicity - dermal

Remarks No results for acute dermal toxicity were presented for the notified polymer or for the analogue polymer. Subchronic testing of the analogue polymer in rats showed no systemic effects from dermal application of a product containing 1 % polymer at 2.0 mL/kg bw five days a week for six weeks, indicative of no dermal toxicity at this level (CIR, 1983).

### 7.3. Acute toxicity - inhalation

Remarks No results for acute inhalation toxicity were presented for the notified polymer or for the analogue polymer. Subchronic testing of the analogue polymer in rats and hamsters showed no systemic effects from exposure to a product containing 4 % polymer at 5.4 mg/m<sup>3</sup> four hours per day, five days a week for thirteen weeks, indicative of no inhalation toxicity at this level (CIR, 1983).

#### 7.4. Irritation – skin

TEST SUBSTANCE	Notified polymer (as a 30.2 % aqueous solution)
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 Chbb: NZW(SPF)
Number of Animals	3
Vehicle	None
Observation Period	3 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

#### RESULTS

<i>Lesion</i>	<i>Mean Score* 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	0.33	1	2	48 hours	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	Two animals showed Draize scores of 2 and one a Draize score of 1 for erythema at 1 hour after patch removal. All signs of irritation resolved by Day 3.
CONCLUSION	The notified polymer is slightly irritating to skin.
TEST FACILITY	BASF Aktiengesellschaft Experimental Toxicology and Ecology (2000b)

#### 7.5. Irritation - eye

TEST SUBSTANCE	30.2 % aqueous solution of notified polymer.
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 HsdIf: NZW(SPF)
Number of Animals	3
Observation Period	3 days
Remarks - Method	A dose of 0.1 mL of the solution was instilled

#### RESULTS

<i>Lesion</i>	<i>Mean Score* 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>	1	0.33	0	2	48 hours	0
<i>Conjunctiva: chemosis</i>	0	0	0	1	1 hour	0
<i>Conjunctiva: discharge</i>	0	0	0	1	1 hour	0

<i>Corneal opacity</i>	0	0	0	0	-	0
<i>Iridial inflammation</i>	0	0	0	0	-	0

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

Remarks - Results	All animals showed Draize scores of 2 for conjunctival redness and 1 for discharge at the 1 hour observation; one animal also showed slight chemosis at this time.
CONCLUSION	The notified polymer is slightly irritating to the eye.
TEST FACILITY	BASF Aktiengesellschaft Experimental Toxicology and Ecology (2000c)

## 7.6. Skin sensitisation

TEST SUBSTANCE	30.2 % aqueous solution of notified polymer.
METHOD	OECD TG 406 Skin Sensitisation – Buehler Test. EC Directive 96/54/EC B.6 Skin Sensitization - Buehler Test.
Species/Strain	Guinea pig/Hsd Poc: DH(SPF)
PRELIMINARY STUDY	Maximum Non-irritating Concentration: 100 %
MAIN STUDY	
Number of Animals	Test Group: 20 female                      Control Group: 10 female
INDUCTION PHASE	Induction Concentration: 100 %
Signs of Irritation	No signs of irritation were seen during induction.
CHALLENGE PHASE	topical application: 100 %
Remarks - Method	
RESULTS	
Remarks - Results	No dermal responses to the notified polymer were seen at challenge in either the test or control animals. Hair was pulled out from the edges of the test site on patch removal due to the adhesive properties of the solution.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.
TEST FACILITY	BASF Aktiengesellschaft Experimental Toxicology and Ecology (2000d)

## 7.7. Repeat dose toxicity

TEST SUBSTANCE	Analogue polymer
RESULTS	A number of subchronic and chronic studies on the analogue polymer have been reported (CIR, 1983). These included a six week dermal toxicity study in rats using a product containing 1 % notified polymer, an oral study using 10.2 mg/L analogue polymer in water using rats and mice for 1 year (average intake 2 – 3 mL/day for mice and 15 – 20 mL/day for rats) and inhalation studies using 5.4 mg/m <sup>3</sup> (4 hours per exposure, 5 days per week) for 90 days in rats and hamsters and up to 0.35 mg/L (9 – 35 minutes per exposure, once a week) for 2 years. No evidence of toxicity was reported from any of the studies.

## 7.8. Genotoxicity - bacteria

TEST SUBSTANCE	30.2 % aqueous solution of notified polymer.
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METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure/Pre incubation procedure
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100. <i>E. coli</i> : WP2 uvrA.
Metabolic Activation System	10 % S9 fraction from the livers of rats pretreated with Aroclor 1254
Concentration Range in Main Test	a) With metabolic activation: 66 - 16500 µg/plate. b) Without metabolic activation: 66 - 16500 µg/plate.
Vehicle	Water
Remarks - Method	Two independent tests were performed for each strain in triplicate; the initial test used the plate incorporation procedure, while the confirmatory test used the pre incubation procedure
RESULTS	
Remarks - Results	No test substance precipitation was seen in any test. Bacteriostatic effects were seen in some cases at 8250 µg/plate and above. No significant increases in the numbers of revertant colonies were seen for any strain, either in the presence or absence of metabolic activation. Appropriate positive controls were used and in all cases resulted in large increases in the number of revertant colonies, confirming the sensitivity of the test system.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BASF Aktiengesellschaft Experimental Toxicology and Ecology (2000e)

#### 7.9. Genotoxicity – in vitro

No test reports were submitted by the notifier.

#### 7.10. Genotoxicity – in vivo

No test reports were submitted by the notifier.

### 8. ENVIRONMENT

#### 8.1. Environmental fate

##### 8.1.1. Ultimate biodegradability

TEST SUBSTANCE	Collacral VAL
METHOD	Combined static CO <sub>2</sub> /DOC test, performed under the protocols of ISO 9439 Annex D.
Inoculum	Activated sludge from WWTP
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	CO <sub>2</sub> evolution and DOC
Remarks - Method	The polymer was incubated with inoculum from sewage sludge for 28 days using sufficient amounts to provide 40 mg/L total organic carbon. For comparison, a reference substance, aniline, was also incubated using the same TOC concentration and inoculum. The biologically produced CO <sub>2</sub> was trapped and measured and the loss of DOC was measured.
RESULTS	
Remarks - Results	Less than 15 % CO <sub>2</sub> was evolved over 28 days. This compared to over 80 % CO <sub>2</sub> evolved from the reference substance after 14 days. In

addition, less than 12 % dissolved organic carbon in the notified polymer was eliminated when incubated over 28 days, compared to 80 to 90 % of DOC in the reference substance eliminated within the first 3 days of incubation with sewage sludge.

**CONCLUSION** 10 – 20 % of the test substance was degraded over the test period. Hence, the test substance is poorly biodegradable, and poorly eliminated from water.

**TEST FACILITY** BASF Aktiengesellschaft Experimental Toxicology and Ecology (2000f)

### 8.1.2. Bioaccumulation

No bioaccumulation test data were provided in the notification dossier. The notified polymer is not readily biodegradable so could persist in the environment. The polymer has a moderate NA molecular weight (500), with 33 % below 500. Molecules of a size greater than 500 are generally poorly absorbed across biological membranes into biological tissue, while molecules smaller than this are better able to cross membrane. Hence, while most of the polymer is not expected to cross biological membranes and bioaccumulate, some molecules of smaller molecular weight may. The polymer is surface active, which could increase wettability of cell membranes, and which may lead to an increase in toxicity of a substance occurring even at very low concentrations (OECD 1981).

## 8.2. Ecotoxicological investigations

### 8.2.1. Acute toxicity to fish

**TEST SUBSTANCE** Collacral VAL

**METHOD** OECD TG 203 Fish, Acute Toxicity Test - static conditions.

**Species** Zebra Fish: *Brachydanio rerio* HAM. and BUCH.

**Exposure Period** 96 hours

**Auxiliary Solvent** None

**Water Hardness** 250 mg CaCO<sub>3</sub>/L

**Analytical Monitoring** None

**Remarks – Method** 10 juvenile Zebra Fish were exposed to nominal concentrations of 0 (control) and 100 mg/L of the notified polymer. The test was carried out in filtered, non-chlorinated municipal water, held at 23°C. Dissolved oxygen levels were in excess of 7.9 mg/L of solution and pH levels were between 8.1 and 8.3.

**RESULTS**

**LC50** ≥100 mg/L at 96 hours.

**NOEC (or LOEC)** ≥100 mg/L at 96 hours.

**Remarks – Results** No adverse effects or fish mortalities were observed at the nominal concentration of 100 mg/L over the test period. No analytical concentration controls were performed to verify the test concentrations. It was assumed that because the substance is completely miscible in water, the nominal concentrations would be maintained. The test concentration showed slight foam formation in the test medium.

**CONCLUSION** The test substance is practically non-toxic to fish.

**TEST FACILITY** BASF Aktiengesellschaft Experimental Toxicology and Ecology (2000g)

### 8.2.2. Acute toxicity to aquatic invertebrates

**TEST SUBSTANCE** Collacral VAL

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

Species	Test - static conditions. <i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	220-320 mg CaCO <sub>3</sub> /L
Analytical Monitoring	No analytical concentration controls were performed to verify the test concentrations because the substance was completely miscible in water.
Remarks - Method	20 daphnids (4 x 5 replicates) were exposed to nominal concentrations of 0 (control), 12.5, 25, 50 and 100 mg/L of the notified polymer. The tests were carried out in ultra-pure, demineralised water kept at 18 to 20°C. Dissolved oxygen levels were always in excess of 3 mg/L of solution and pH levels were between 7.5 and 8.5.
RESULTS	
LC50	>100 mg/L at 48 hours
NOEC (or LOEC)	>100 mg/L at 48 hours
Remarks - Results	No test animals were captured in the surface film and none were observed to be immobile at the test concentrations used over the observation period.
CONCLUSION	The test substance is practically non-toxic to <i>Daphnia</i> .
TEST FACILITY	BASF Aktiengesellschaft Ecology and Environmental Analytics (2000h)

### 8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Collacral VAL
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	<i>Scenedesmus subspicatus</i>
Exposure Period	72 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Chlorophyll-a-fluorescence
Remarks - Method	The test was conducted against an initial inoculation density of $1 \times 10^4$ cells/ml of <i>Scenedesmus subspicatus</i> using nominal concentrations of 0 (control), 6.25, 12.5, 25, 50 and 100 mg/L respectively of the notified polymer. The tests were carried out in demineralised water at 23°C, under a light intensity of 60-120 $\mu\text{E}/(\text{m}^2.\text{s})$ at wavelength 400-700nm. The pH variation ranged between 7.9 and 8.1 over the test period. Determination of the mean fluorescence was carried out after 0, 24, 48, and 72 hours. The biomass growth rate was calculated for each concentration level over the total duration of the test period and compared to untreated samples.
RESULTS	
Remarks - Results	No effects were observed on the development of biomass ( $E_bC$ ) or on the growth rate ( $E_rC$ ) of the algae at any of the test concentrations up to 100 mg/L over the test period.
CONCLUSION	The test substance is practically non-toxic to green algae.
TEST FACILITY	BASF Aktiengesellschaft Experimental Toxicology and Ecology (2000i)

### 8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Collacral VAL
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sewage sludge
Exposure Period	30 minutes
Remarks – Method	An Activated Sludge Respiration Inhibition Test was conducted against 1

g/l dry inoculum from activated sludge from municipal sewage, using nominal concentrations of 1, 10 and 100 mg/L of the notified polymer. The test was carried out at a temperature of 20°C, and with pH values varying between 6.8 to 7.4, and a dissolved oxygen concentration prior to measurement of 6.5 mg/L. The oxygen consumption of micro-organisms exposed to the test substance was measured after 30 minutes incubation time, and compared to that of micro-organisms in a blank control and a reference substance (3,5-dichlorophenol) incubated under the same conditions. The variation in consumption between the test substance and a blank control after 30 minutes was found to be less than 11 %, while the EC<sub>50</sub> of the reference substance was determined to be in the range 5 - 30 mg/L, therefore the test was deemed valid.

**RESULTS**

IC50 1000 mg/L

NOEC 1000 mg/L

Remarks – Results The results of the test indicate no inhibition of oxygen consumption by micro-organisms in sewage sludge under the test conditions, using concentrations of up to 1000 mg/L of the notified polymer.

**CONCLUSION**

The test substance is not toxic to micro-organisms in sewage sludge.

**TEST FACILITY**

BASF Aktiengesellschaft Ecology and Environmental Analytics (2000j)

**9. RISK ASSESSMENT****9.1. Environment****9.1.1. Environment – exposure assessment**

Usage patterns indicate that most of the polymer will be bound up with the surface coatings and deposited on floors and other surfaces, where it will be inert. A portion of the polymer may be released into on-site effluent treatment facilities during formulation at the 2 factory sites. A small amount may also be released to the municipal sewer through washing from brushes during application of the end product by individual tradespeople. Such release is expected to be diffuse and occur throughout Australia.

The daily predicted environmental concentration (PEC) released from on-site effluent treatment systems is  $1.6 \times 10^{-3}$  µg/L, assuming the treated effluent water is released to a treatment plant with a 250 ML/day capacity, and assuming no biodegradation of the polymer. The PEC would be significantly reduced by dilution once the treated trade-waste effluent is released into the municipal sewer. The daily PEC of notified polymer in the municipal sewer from nationwide use of the end product will be  $9.5 \times 10^{-7}$  µg/L. This value assumes a water usage of 150 L per person by a population of 19 million.

The notified polymer is colloidal miscible in water and is soluble in organic solvents. Thus upon entering sewage treatment facilities the colloids are expected to adsorb to organic matter and eventually settle out into sludge.

**9.1.2. Environment – effects assessment**

The notifier provided four ecotoxicity test reports, conducted according to OECD guidelines, on the toxicity of the polymer solution, Collacral VAL. All test showed LC<sub>50</sub> values > 100 mg/L indicating the substance is practically non-toxic to aquatic organisms. A Predicted No Effect Concentrations (PNEC) for aquatic organisms, calculated from the acute toxicity of the most sensitive species and using a safety factor of 100, is > 1 mg/L.

**9.1.3. Environment – risk characterisation**

The polymer is not expected to pose a threat to aquatic organisms provided it is not released directly into natural waters, and is introduced into sewage systems at the low concentrations anticipated by the notifier. The estimated daily PEC's for the local on-site treatment facilities and for the municipal sewer are  $1.6 \times 10^{-3}$  µg/L and  $9.5 \times 10^{-7}$  µg/L respectively. The notified

polymer is practically non-toxic to aquatic organism. A PNEC for aquatic organisms, calculated from the acute toxicity of the most sensitive species and using a safety factor of 100, is  $> 1$  mg/L. Thus the PNEC/PEC ratios for the on-site treatment facilities and the sewer are both significantly less than one, indicating no immediate concern for aquatic organisms.

The local PEC would be further significantly reduced once released into the municipal sewer from trade waste treatment facilities. The national PEC would be further reduced by dilution with the natural receiving waters. Thus the concentrations of the notified polymer eventually released into the natural environment each week will be extremely low, and many orders of magnitude lower than the highest nominal exposure concentrations showing no adverse effects in the toxicity tests.

In the sewer, the polymer is expected to partition mainly into sludge, from where it will eventually be disposed of in landfill with solid wastes. The polymer is not readily biodegradable under aerobic conditions and is also poorly eliminated abiotically. Hence, in soil environments, the polymer will likely undergo slow biotic and abiotic degradation. The esters comprising part of the polymer are expected to eventually hydrolyse. The polymer is not expected to enter waterways through leaching from the soil, but to adsorb to soil organic matter.

If incineration of the substance occurs at landfill sites, combustion may result in the production of substances such as water, carbon monoxide, carbon dioxide and oxides of nitrogen.

Instructions in the MSDS are adequate to limit the environmental exposure from spills, and therefore the environmental hazard from possible accident spills should be low. The environmental hazard from the disposal of the product containing the polymer is rated as negligible.

## **9.2. Human health**

### **9.2.1. Occupational health and safety – exposure assessment**

Exposure may occur for labourers during decanting the 30 % notified polymer solution from the imported containers into mixing vessels and while filling the maximum 2 % solution into containers for trade sale. Laboratory technicians may have dermal exposure to the product containing a maximum of 2 % notified polymer. Accidental dermal or ocular exposure is probable for waterproofing tradespeople during application of the product.

Exposure will be predominantly dermal due to the low volatility of the notified polymer and the high viscosity of the notified polymer solution and end-use products, which will reduce splashing and aerosol formation. A high level of personal protective equipment will be used during reformulation, which will reduce exposure for these workers; however no details of protective measures used by application tradespeople was provided by the notifier. Application is likely to occur under poorly controlled conditions, and there may be significant opportunities for dermal or ocular exposure to the end-use product for these workers.

### **9.2.2. Public health – exposure assessment**

The notified polymer is imported for industrial reformulation and application only. The likelihood of public exposure to the notified polymer during transport, handling and end-use is very low. After application, the end-use product, which contains a very low concentration of the notified polymer, forms a waterproofing membrane on the surface of concrete or fibre cement substrates.

### **9.2.3. Human health - effects assessment**

Limited test data on the notified polymer (as a 30 % aqueous solution) was provided by the notifier. It was found to be of low acute oral toxicity in rats ( $LD_{50} > 2000$  mg/kg bw notified polymer). It was slightly irritating to rabbit skin and eyes, producing skin erythema and conjunctival redness which resolved by day 3. No evidence of sensitisation was seen in a non-adjuvant study in guinea pigs. The notified polymer was not mutagenic in a bacterial assay.

A summary of toxicity data on an analogue polymer which is close in composition to the notified polymer was provided (CIR, 1983). It is not clear whether the analogue polymer used in each of the studies reported in the summary would resemble the notified polymer in molecular weight distribution and therefore potential to be absorbed by the skin or other biological membranes. The summary provided details of a number of repeat dose toxicity studies on the analogue polymer, by inhalation and dermal and oral administration. No effects due to the polymer were seen in any of the studies. The summary also addresses the mutagenicity of the constituent



monomers of the analogue polymer; these were not considered mutagenic in several tests. The analogue was considered to be safe for use in cosmetic products.

Based on the results of the testing on the notified polymer, and on the conclusions drawn in the summary of results on the analogue polymer, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

#### **9.2.4. Occupational health and safety – risk characterisation**

The notified polymer as a 30 % solution is slightly irritating to rabbit skin and eyes, and therefore dermal and ocular exposure to the concentrated solutions should be avoided. The concentrated solutions will be handled for short periods, with use of appropriate protective equipment, and little risk to the workers involved in reformulation is therefore expected. During testing, packaging and application, a much lower concentration of notified polymer (maximum 2 % but normally much lower) will present in the products being handled, and the risk of irritation due to contact with the notified polymer will be much lower than for the concentrated solutions, although the products may contain other ingredients which contribute to hazard.

The highest likelihood of exposure is for the workers involved in application of the end-use products, but the risk of adverse effects due to contact with the notified polymer will be low due to the low concentration of notified polymer in these products.

#### **9.2.5. Public health – risk characterisation**

Once the waterproofing membrane formulation has dried, the notified polymer in the film is no longer bioavailable. Hence, the effect of the notified polymer on public health 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* (NOHSC, 1999).

#### **10.2. Environmental risk assessment**

The low environmental exposure, combined with the low toxicity of the polymer indicates the polymer is not likely 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 for industrial reformulation and application as described in the notification.

### **11. MATERIAL SAFETY DATA SHEET**

#### **11.1. Material Safety Data Sheet**

The MSDS of the notified polymer solution provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as 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 solution provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

## 12. RECOMMENDATIONS

### CONTROL MEASURES

#### Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation:
  - impervious gloves, safety eyewear and industrial clothing and footwear

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 in landfill or by incineration according to local and State regulations.

#### Emergency procedures

- Spills/release of the notified polymer should be handled by the methods outlined in the MSDS.

### 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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