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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Desmophen NH1520/Chemical in Desmophen NH 1521

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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Desmophen NH1520/Chemical in Desmophen NH 1521

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Bayer Australia Limited (ABN 22 000 138 714)
500 Wellington Road
Mulgrave North VIC 3170

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (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
Molecular Weight
Spectral Data
Purity and Identity of Impurities
Details of Use
Introduction Volumes
Identity of Recipient

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point/Freezing Point
Water Solubility
Hydrolysis as Function of pH
Adsorption/Desorption
Dissociation Constant
Genotoxicity – *in vitro*
Bioaccumulation
Algal Growth Inhibition Test

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES

Environment Canada (2000)
USA (1991): (Notice of commencement (NOC) 1992)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Desmophen VP LS 2973 (contains 90% notified chemical)
Desmophen VP LS 2975
Desmophen VP LS 2958

Hardener trial product LS 2959
ZWI 579 (100% notified chemical)
Desmophen PAC XP 7052 E (contains 90% notified chemical in n-butyl acetate)
Desmophen XP 7052 (contains 90% notified chemical in n-butyl acetate)

MARKETING NAME(S)
Desmophen NH 1520 (100% notified chemical)
Desmophen NH 1521 (contains 90% notified chemical in n-butyl acetate)

METHODS OF DETECTION AND DETERMINATION

Remarks The identity of the chemical was confirmed using Infrared spectroscopy, Nuclear Magnetic Resonance spectroscopy and UV-Visible spectroscopy. The levels of impurities were determined by High Performance Liquid Chromatography and Gravimetric Determination.

3. COMPOSITION

DEGREE OF PURITY
> 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities are present at below the relevant cut offs for classification of the notified chemical as a hazardous substance.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia, but will be imported as a component in the reactive thinner Desmophen NH 1521 (at a concentration of 90%) or as Desmophen NH 1520 (at concentration of 100%) in sealed containers (closed head 205 L steel drums). Following import the notified chemical will be transported by road to individual manufacturing (reformulation) customer site(s).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 50	< 50	< 50	< 50	< 50

USE
The notified chemical is an amino functional reactive thinner for low volatile organic compound (VOC) two component polyurethane/urea paint systems for maintenance, automotive and light industrial applications.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
The notified chemical will initially be imported through Brisbane, by wharf.

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will not be manufactured in Australia. It will be imported by the notifier, stored in a contract warehouse in Queensland and then distributed to the customer(s) as required.

TRANSPORTATION AND PACKAGING
Desmophen NH 1521 and Desmophen NH 1520 will be imported in 205 L sealed closed head steel

drums and transported by road from wharf to the storage facility or the reformulation site.

5.2. Operation description

Paint Formulation

Formulation of the notified chemical into paint products will involve transfer of notified chemical by metered dosing to a mixing vessel and mixing with other ingredients in a sealed vessel fitted with a high-speed mixer and local ventilation system. Each batch is to be quality checked and adjustments made as required. The resultant paint is filtered prior to being dispensed into 205 L closed head drums or 20 L steel pails sealed with a metal ring lock under exhaust ventilation for supply to customers. The final concentration of the notified chemical in the final product will be < 6% for automotive coatings and < 65% for floor coatings. Paint products containing the notified chemical will be warehoused at the paint manufacturer's site and distributed to end-users.

Automotive Application

At the end users site, the 205 L steel drums will be opened under local fume extraction. The second component of the 2-pack system will be added at a 5:1 ratio (resulting in chemical concentration of < 5%) to the same container, the contents will be stirred using a mechanical stirring paddle at slow speed and the lid will be replaced. Pumping equipment will be inserted into the drum via an open bung and connected to the spray equipment. Spraying of the vehicles will take place within an automated, enclosed spray booth. Once spraying is completed, the paint is heat cured.

Floor Coating Application

Professional tradesmen will open 20 L pails containing the floor coating. They will add the second component of the 2-pack system at a 5:1 ratio (resulting in notified chemical concentration of < 55%) to the same container, the contents will be stirred using a drill and a stirring paddle at slow speed. The coating will be applied to the concrete floor using a paint brush or roller.

Maintenance Applications (metal or concrete substrates)

Professional tradesman will open 20 L pails of paint, add the second component of the 2-pack system at a 5:1 ratio (resulting in notified chemical concentration of < 55%) to the same container, the contents will be stirred using a drill and a stirring paddle at slow speed. The coating will be applied to metal or concrete structures such as bridges and buildings. The method of application will mostly involve the use of brushes and rollers, but may involve spray painting. For spray painting, the mixed paint will be manually poured into a 5 L spray gun reservoir and used.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Storage	4	2-3	10-15
Paint formulation			
Paint make up	3	8	100
QC testing	1	8	100
Filling into containers	3	8	100
Maintenance	2	8	100
End-use			
Automotive	100	12	200
Floor applicators	500	8	200
Maintenance coating	500	8	300

Exposure Details

Transport and Storage

Exposure to the notified chemical during transportation and storage is unlikely, however, exposure may result in case of an accidental spill or leak from the pails or drums.

Paint formulation

Paint make up

Workers may be exposed to the notified chemical via dermal and ocular exposure due to drips, spills and splashes, during charging of mixer and blending. Workers will wear coveralls, goggles and

impervious gloves. Inhalation exposure due to aerosols released during blending is considered to be unlikely due to the sealed vessel and exhaust ventilation systems. Where required, a respirator will be worn.

QC testing
Dermal and ocular exposure is possible from drips, spills and splashes during batch adjustment and when taking and testing samples. Workers wear laboratory coats, goggles and impervious gloves to minimise exposure.

Filling into drums
Dermal exposure may be possible due to drips and spills when connecting filling lines. The paint is filled into drums under local exhaust ventilation and workers wear overalls, goggles and impervious gloves.

Formulation maintenance workers
There is possible of skin contact during equipment maintenance. Workers wear coveralls, goggles and gloves.

Automotive Application
Exposure to the paint containing the notified chemical will mostly occur during opening of containers, mixing and connecting and unconnecting pumping equipment. The spraying operation is conducted within an automated, enclosed spray booth, thus exposure of the workers during this operation will be minimal. Workers will wear anti-statistic flame retardant overalls, anti-static footwear, impervious gloves, eye protection and an air fed breathing mask or respirator if local exhaust ventilation is inadequate.

Worker exposure to the notified chemical in dried paints is likely to be minimal, as the notified chemical will be encapsulated as part of the cured paint film.

Floor Coating Application
Professional flooring workers may be exposed to the paint during opening of containers, mixing and applying the paint. They may also be exposed during cleaning of equipment. Exposure is likely to be via the dermal route. Workers will wear overalls, rubber gloves, safety glasses and a suitable respirator.

Maintenance Applications (metal or concrete substrates)
Professional maintenance workers may be exposed to the paint during opening of containers, mixing and applying the paint. They may also be exposed during cleaning of equipment. Exposure is likely to be via the dermal route, however, there is the potential for inhalation exposure where paint is applied using a spray gun. Workers will wear overalls, rubber gloves, safety glasses and a suitable respirator.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia. Desmophen NH 1521 and Desmophen NH 1520 will be imported in 205 L sealed closed head steel drums. The notified chemical will be reformulated into paint products at the customer's paint manufacturing site. Releases to the environment are not expected to occur during transport and warehousing, except in unlikely event of an accident. In the worst case the contents of a 205 L drum may be spilled. Any spills will be contained and collected using adsorbent material, placed in a sealed 205 L drum and disposed off to landfill.

During reformulation into automotive and floor coatings, residual material in empty drums is estimated to account for 1% of import volume (500 kg/year). The empty drums will be disposed off to landfill by a waste contactor. Spills and leaks and washings from process equipment are expected to account for a further 1% of import volume (500 kg/year). These wastes will be collected and sent off site for disposal to landfill. No material will be released to sewer.

RELEASE OF CHEMICAL FROM USE

Automotive

At the end-users site the empty 205 L steel drums, containing the residual paint, will account for 0.06% of the import volume (30 kg/year). Any overspray will be collected via filters on the fume extraction equipment connected to the spray booth. The overspray is expected to account for 10% of the import volume (5000 kg/year). The filters are collected periodically and disposed of to landfill.

Floor Coatings

The empty 20 L containers will contain approximately 2.5% residual material accounting for 150 kg of the notified chemical per year. This material will be mixed with the second part of the polyurethane coating system and allowed to cure. The cured solid material will be disposed of to landfill along with the container. Any rollers and paint brushes will be cleaned using a solvent. The washings will be collected and disposed of to a liquid waste facility or incinerated.

Maintenance Applications (metal or concrete substrates)

The empty 20 L containers will contain approximately 2.5% residual material accounting for 150 kg of the notified chemical per year. This material will be mixed with the second part of the polyurethane coating system and allowed to cure. The cured solid material will be disposed of to landfill along with the container. Any rollers and paint brushes or spray equipment will be cleaned using a solvent. The washings will be collected and disposed of to a liquid waste facility or incinerated.

Overspray may contribute to the environmental release. For outdoor spraying, the overspray is estimated to be as much as 20% of the paint volume. This is estimated to equate to 500 kg/year (based on 5% of import volume being used in this type of application and 20% overspray). The overspray droplets are likely to land on immediate surrounding areas, which are likely to be covered by a protective drop sheet, but may be carried by the wind and be dispersed throughout a wider area. As the paint droplets cure, the notified chemical will be immobilised within the cured paint matrix.

5.5. Disposal

Empty containers and any spills and wastes will be disposed of to landfill. Solvent washings may be incinerated.

Paint Manufacture

Approximately 1000 kg of waste notified chemical will be generated annually during the manufacture of the paint. This is likely to be disposed of to landfill but some may be incinerated.

Automotive

Due to the application of paint, up to 5000 kg of notified chemical will go to landfill across Australia from landfill. Residues in paint containers will account for up to a further 30 kg which will either be disposed of to landfill or incinerated in container recycling.

Floor Coatings

Approximately 150 kg per annum of the notified chemical will be disposed of to landfill as cured residues in empty paint containers. The floor finish will cure to form an inert coating on the surface of the floors. It will remain on the floors until it is gradually worn down by human traffic, being slowly dispersed on shoes etc. At the end of its useful life it will be removed by the professional floor sanders and presumably replaced by another coat of a similar product. The coating containing the notified chemical will be broken up into solid particulate matter in the sanding/removal process and most likely disposed to landfill.

Maintenance Applications (metal or concrete substrates)

Approximately 150 kg per annum of the notified chemical will be disposed of to landfill as cured residues in empty paint containers. The paint will cure to form an inert coating on the surfaces to which they are applied. It will remain on the surfaces and gradually worn away. At the end of its useful life it will be removed by the professionals and presumably replaced by another coat of a similar product. The coating containing the notified chemical will be broken up into solid particulate matter in the sanding/removal process and most likely disposed to landfill.

5.6. Public exposure

Neither the notified chemical nor formulated paint products will be sold to the public. The public will only come into contact articles or surfaces which have treated with coatings containing the notified chemical.

Where paint is applied by spray in an outdoor area, indirect inhalation exposure to the notified chemical cannot be ruled out.

6. PHYSICAL AND CHEMICAL PROPERTIES

The tests for density, vapour pressure and fat solubility were conducted on a 90% solution of the notified chemical in n-butylacetate.

Appearance at 20ºC and 101.3 kPa Colourless to faint yellow liquid

Melting Point/Freezing Point Not determined

Remarks A determination of the solidification point is not possible due to the high viscosity of the substance at low temperatures.

Boiling Point > 240ºC

Remarks The notified chemical is reported to thermally degrade at temperatures higher than 240 ºC. The boiling point of Desmophen NH 1521 is expected to be similar to n-butylacetate (127 ºC). Test conducted in compliance with the OECD principles of Good Laboratory Practice (GLP).

TEST FACILITY Bayer (1991a)

Density 1061.9 kg/m^3 at 20ºC

METHOD EC Directive 92/69/EEC A.3 Relative Density.

Remarks Determined using an oscillating densitometer. Test conducted in compliance with the OECD principles of GLP.

TEST FACILITY Bayer (1992a)

Vapour Pressure

$8.5 \times 10^{-6} \pm 4.6 \times 10^{-6}$ kPa at 50°C

$2.1 \times 10^{-6} \pm 1.4 \times 10^{-6}$ kPa at 25°C

$1.6 \times 10^{-6} \pm 1.0 \times 10^{-6}$ kPa at 20°C

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.

Remarks Determined using a vapour pressure balance. Test conducted in compliance with the OECD principles of GLP.

TEST FACILITY Bayer (1991b)

Water Solubility Not determined

Remarks The notifier claims that the determination of the water solubility was not possible due to hydrolysis of the notified chemical in aqueous solution. It should be noted that concentrations up to 284 mg/L were measured during the fish toxicity study. The method of analysis was not reported.

Fat (or n-octanol) Solubility Miscible

Remarks The study was provided in German with only an English translation of a summary. The fat used was Standard fat HB 307. Test conducted in compliance with the OECD principles of GLP.

TEST FACILITY Bayer (1992b)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*t½ hours*
4	50	9-24
7	50	9-24
9	50	9-24

Remarks These are preliminary results from an interim study with little detail provided. The concentrations were determined using HPLC-MS. The MS detection was performed in single ion mode and is highly specific for test material and the hydrolysis products were not identified. The report indicates that the hydrolysis was fastest at pH 9, but this cannot be confirmed.
TEST FACILITY Bayer (2005)

Partition Coefficient (n-octanol/water) Log Pow at 20°C = 6.4 (calculated)

METHOD Calculation
Remarks Determination via the required method was not possible due to the hydrolysis of the substance in aqueous solution (preliminary test). Log Pow was calculated with DAYMENUS 3.6. (Daylight Chemical Information Systems, INC).
TEST FACILITY Bayer (1992c)

Adsorption/Desorption log K_{oc} = 4.2 – 4.9 at 25°C (calculated)

METHOD The log Koc was calculated using the Log Pow = 6.4 using ACD software.
Remarks The notified chemical is expected to bind strongly to organic matter in soil.
TEST FACILITY Cantox Inc., Canada

Dissociation Constant pKa = 7.35 and 6.74 (estimated)

METHOD The pKa values were estimated based on the structure using the Advanced Chemistry Development ACD/pKa Predictor 2.7 software.
Remarks As such at neutral pH or below, the notified chemical will be cationic but at slightly basic pH, the notified chemical will not carry a charge.
TEST FACILITY Cantox (1999)

Particle Size Not applicable

Remarks Notified chemical is a liquid

Flash Point 110 °C at 1006 kPa

METHOD A.9 EEC Directive 84/449 Flash Point.
Remarks Determined using Pensky-Martens closed cup method. Test conducted in compliance with the OECD principles of GLP.

The notified chemical is classified as a C1 combustible liquid (NOHSC, 2001)
TEST FACILITY Bayer (1991c)

Flammability (Contact with Water) Does not evolve flammable gas

METHOD A.12 EEC Directive 84/449 Flammability (Contact with Water)
Remarks

Test conducted in compliance with the OECD principles of GLP.

All steps listed in the protocol were completed. Spontaneous ignition did not take place in any step of the test procedure and the amount of gas produced (if any) was below a rate of 1 litre/kg of the substance per hour.

Based on the presence of other ingredients Desmophen NH 1521 is classified as flammable according to the Australian Dangerous Goods classification (FORS, 1998).

TEST FACILITY Bayer (1991c)

Autoignition Temperature 335ºC

METHOD A.15 EEC Directive 84/449 Auto-Ignition Temperature (Liquids and Gases)
Remarks Test conducted in compliance with the OECD principles of GLP.
TEST FACILITY Bayer (1991c)

Explosive Properties Not explosive

METHOD A.14 EEC Directive 84/449 Explosive Properties.
Remarks Explosive potential of the notified chemical was studied under heating, mechanical shock and friction conditions. Test conducted in compliance with Good Laboratory Practice standards. No explosion was recorded in any test.
TEST FACILITY Bayer (1991d)

Reactivity

Remarks The notified chemical is expected to be stable under normal conditions of use. The notified chemical thermally degrades above 240 ºC.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	low toxicity, LD50 >2000 mg/kg bw
Rat, acute dermal	low toxicity, LD50 >2000 mg/kg bw
Rat, acute inhalation	low toxicity, LC50 >4.224mg/L/4 hour /mild respiratory tract irritant.
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	evidence of sensitisation
Rat, repeat dose oral toxicity – 29 days.	NOAEL 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro	not determined
Genotoxicity – in vivo erythrocyte micronucleus test	non clastogenic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD This study was conducted in accordance with EEC Directive 84/449/EEC (OJ No. L251, 19.09.84)

Species/Strain Rat/ Wistar

Vehicle Peanut oil

Remarks - Method No significant protocol deviations from OECD TG 401 Acute Oral Toxicity – Limit Test. Test conducted in compliance with the OECD principles of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0/10

LD50 >2000 mg/kg bw

Signs of Toxicity There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period.

Effects in Organs There were no remarkable necropsy findings.

Remarks - Results

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

TEST FACILITY Bayer (1990a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD This study was conducted in accordance with EEC Directive 84/449/EEC (OJ No. L251, 19.09.84)

Species/Strain Rat/Wistar

Vehicle Test substance administered as supplied

Type of dressing Occlusive

Remarks - Method No significant protocol deviations from OECD TG 402 Acute Dermal Toxicity – Limit Test. Test conducted in compliance with the OECD principles of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	A slight skin reddening at the application site was observed in 2 males and 3 females. In the case of 1 female this reddening persisted until the 5th day of observation, in the case of the other animals it appeared only on the day following the treatment.
Signs of Toxicity - Systemic	There were no deaths or test-substance related clinical signs. Body weight gain in females was retarded.
Effects in Organs	There were no remarkable necropsy findings.
Remarks - Results	

CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Bayer (1992d)

7.3. Acute toxicity – inhalation

TEST SUBSTANCE	Notified chemical (~90%) in n-butylacetate
METHOD	OECD TG 403 Acute Inhalation Toxicity. EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation).
Species/Strain	Rat/Wistar
Vehicle	Test substance administered as supplied
Method of Exposure	Oro-nasal exposure.
Exposure Period	4 hours
Physical Form	liquid aerosol
Particle Size	MMAD: 1.4 – 1.7 μm respirable mass fraction (≤3 μm): 83.7-91.4%
Remarks - Method	Deviations from protocol: Only two dose concentrations were tested. Test conducted in compliance with the OECD principles of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Concentration mg/L*		*Mortality*
		Nominal	*Actual*	
I	5 per sex	0	0	0
II	5 per sex	1	1.436	0
III	5 per sex	5	4.224	0

LC50	>4.224 mg/L/4 hours
Signs of Toxicity	Bradypnea, laboured and irregular breathing pattern, bristled and ungroomed hair-coat, reddened nostrils, reduced motility and hind limbs which were unable to support body weight were observed in group 3 animals. These effects were resolved within the first post-exposure week. Rats exposed to the test substance experienced a concentration-dependent decrease in body temperature (hyperthemia). There were no appreciable differences in the susceptibility of males and females.
Effects in Organs	There were no remarkable necropsy findings.
Remarks - Results	The contribution of the n-butyl acetate could not be resolved. Inhalation of respiratory irritants is known to induce reflex changes in breathing pattern and cardiac output and are reported to be associated

with the decline in the metabolic rate and body temperature of rodents.

The LC50 range for classification of aerosols as 'harmful by inhalation' is 1-5 mg/L/4hr. Although the high dose falls in this range, it is likely that as no mortalities were observed during the study, the LC50 would be > 5 mg/L/4hr.

CONCLUSION The notified chemical is of low toxicity via inhalation.
The notified chemical is a mild respiratory tract irritant.

TEST FACILITY Bayer (1998a)

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 6
Vehicle Test substance administered as supplied
Observation Period 14 days
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations. Test conducted in compliance with the OECD principles of GLP.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1.2	2	14 days	1
Oedema	0	0	N/A	0

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

Remarks - Results Well-defined erythema was observed in four of the six animals. Slight to well defined erythema was observed in 3 animals after seven days with the effects fully reversed in all but one animal by day 14.

CONCLUSION The notified chemical is slightly to moderately irritating to the skin.

TEST FACILITY Bayer (1991e)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 21 days
Remarks - Method No significant protocol deviations. Test conducted in compliance with the OECD principles of GLP. Fluorescein was used to facilitate corneal observations.

RESULTS

Lesion	*Mean Score** *Animal No.*	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*

	1	2	3			
Conjunctiva: redness	0.3	0.3	0.3	1	<48 hours	0
Conjunctiva: chemosis	0	0	0	1	< 24 hours	0
Conjunctiva: discharge	0	0	0	2	< 24 hours	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Bayer (1991e)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – Magnusson and Kligman method
EEC Directive 84/449/EEC (OJ No. L251, 19.09.84)

Species/Strain Guinea pig/Bor:DHPW

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 5 % (w/v) in polyethylene glycol 400
topical: 50% (w/v) in polyethylene glycol 400

MAIN STUDY

Number of Animals Test Group: 20 Control Group: two groups of 10 (one for each challenge)

INDUCTION PHASE Induction Concentration:
intradermal: 5 % (w/v) in polyethylene glycol 400
topical: 50% (w/v) in polyethylene glycol 400

Signs of Irritation The test sites were pre-treated with 10% sodium lauryl sulphate 24-hours before topical induction. After the topical induction two animals showed an open wound at the application area on day nine. On day 10 the application area of six animals were scabbed over. These scabs stayed up to day 16.

CHALLENGE PHASE

1st challenge topical: 50% (w/v) in polyethylene glycol 400

2nd challenge topical: 25% and 12% (w/v) in polyethylene glycol 400

Remarks - Method Deviation from protocol:

A 50% test substance formulation instead of undiluted test substance was used for topical induction in the preliminary test by mistake. This 50% concentration was taken forward to the main study and used where the undiluted test substance may have been more appropriate.

Test conducted in compliance with the OECD principles of GLP.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	50%	17/20	9/10	-	-
	25%	-	-	10/20	4/20
	12%	-	-	7/20	4/20
Control Group	50%	0/10	0/10	-	-

	25%	-	0/10	0/10
	12%	-	0/10	0/10

Remarks - Results: After the first challenge very mild to clearly visible skin reddening was observed in 85% of the test substance animals. After the second challenge, very mild to clearly visible skin reddening was observed in 50% and 35% of the test substance animals challenged with 25% and 12% test substance respectively. A scaly administration site was observed in some animals.

CONCLUSION: There was evidence indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY: Bayer (1992e)

7.7. Repeat dose toxicity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain: Rat/Wistar
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 29 days
Dose regimen: 7 days per week
Post-exposure observation period: 14 days
Vehicle: Polyethylene glycol 400
Remarks - Method: The doses applied were based on a purity of 91.6%, as the actual purity was later determined to be 94%, the dosages applied were in fact higher than that stated below by about 2.4%.

The doses were selected based on a dose range finding study. No macroscopic lesions were observed in 6 animals dosed with 1000 mg/kg bw for 7 days.

Deviations from protocol:
Sensory reactivity to stimuli not reported.
The organ weights of epididymis and thymus were not reported.
Histopathological examinations were performed on the heart, liver, spleen, adrenals and kidneys.

Test conducted in compliance with the OECD principles of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 per sex	0	0
II (low dose)	5 per sex	40	0
III (mid dose)	5 per sex	200	0
IV (high dose)	5 per sex	1000	0
V (control recovery)	5 per sex	0	0
VI (high dose recovery)	5 per sex	1000	0

Mortality and Time to Death
No mortality was observed during the treatment or recovery phases.

Clinical Observations
No substance-related clinical signs were observed during the treatment period or the recovery. There was no

significant difference in body weight gain and food and water consumption in treated animals when compared to controls.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry

Alkaline phosphatase levels were significantly increased in group IV females (30%, P<0.05) and increased but not significantly in group IV males (22%) when compared to controls. Creatine levels were significantly reduced in group IV males (15%, P<0.01) when compared with controls. A similar reduction was not observed in group IV females. Alkaline phosphatase and creatine levels were not significantly different in the high dose recovery animals when compared to controls. All other significant differences in clinical chemistry parameters noted were without relation to dose and therefore not considered to be treatment related.

Haematology

The thrombocyte count was significantly increased in group IV males (9%, P<0.05)) and females (25%, P<0.01) when compared to controls. A similar increase was not observed in high-dose recovery animals. Although mean corpuscular haemoglobin concentration was significantly increased (1.8%, P<0.05)) in group IV females, levels found were within the normal range and hence are considered to be incidental. All other haematological parameters did not differ significantly from the control values.

Urinalysis

There were no significant findings in any of the parameters in any of the treated animals.

Effects in Organs

Organ weights

A significant increase in absolute liver weight was observed in group IV males (16%, P<0.05) and females (24%, P<0.05). Relative liver weights were also increased in these groups (16% in males and 12% in females) although this was not significant in females. A similar increase was not observed in high-dose recovery animals. All other significant differences in organ weight parameters noted were without relation to dose and therefore not considered to be treatment related.

Macrosopic Findings

There were no remarkable necropsy findings.

Histopathology

There were no remarkable histopathological findings.

Remarks – Results

Clinical Chemistry

The differences observed in creatine and alkaline phosphatase levels in high dose group animals were not considered to be toxicologically relevant as the levels were within the range of historical controls.

Haematology

The increase in thrombocyte count in high dose animals was considered not to be toxicologically significant as the differences are not biologically significant in males and the mean value in females is influenced by only one relatively high value and values were within the range of historical controls.

Organ weight

As the increase in liver weight was not accompanied by any histopathological change and appeared to reverse during the recovery phase, this effect may be interpreted as adaptive in nature.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the absence of adverse treatment related effects.

TEST FACILITY Bayer (1992f)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

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
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	S9-Mix from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 8 - 5000 µg/plate b) Without metabolic activation: 8 - 5000 µg/plate
Vehicle	Ethanol
Physical Form	Gas/vapour
Remarks - Method	Deviations from Protocol: Neither *S. typhimurium* strain T102 or *E.coli* WP2 strains which may detect cross-linking mutagens were included in the assay. 2-Aminoanthracene was used as the sole indicator of the efficacy of the S9-mix. The following positive controls were used in the absence of S9-mix: Nitrofurantoin (TA100) 4-nitro-1, 2-phenylene diamine (TA1537 and TA98) Test conducted in compliance with the OECD principles of GLP.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	-			
Test 1		1000 (TA1537), 8 (TA 98)	5000 (All strains)	negative
Test 2			5000 (All strains)	negative
Present	-			
Test 1		>5000	5000 (All strains)	negative
Test 2		1000 (TA1537)	5000 (All strains)	negative

Remarks - Results	The reported cytotoxicity was based on a reduction in background lawn. It is stated that there was an indication of a bacteriotoxic effect at all tested doses. 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 activation. Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Bayer (1991f)

7.9. Genotoxicity – in vitro

Not determined

7.10. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.

Species/Strain: Mouse/Bor: NMRI

Route of Administration: Intraperitoneal injection

Vehicle: Test substance administered as supplied.

Remarks - Method: No significant protocol deviations. With one exception the study conforms to the OECD principles of GLP. The deviation was that no data were available on complete analytical characterisation of the test substance.

Limit test performed. Animals are treated with the test substance once. Dose selected based on a preliminary test in which five animals were intraperitoneally administered 5 ml/kg, 10ml/kg, 20 ml/kg pure test substance and 2500 mg/kg notified chemical in corn oil.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (negative control, PS)	5 per sex	0	24
II	5 per sex	5345*	16
III	5 per sex	5345*	24
IV	5 per sex	5345*	48
V (positive control, CP)	5 per sex	20	24

PS= physiological saline CP=cyclophosphamide.
* based on 5 mL of test substance administered and density of 90% solution of notified chemical.

RESULTS

Doses Producing Toxicity: Treated animals (group II, III, IV) showed the following signs of toxicity: apathy, roughened fur, distended abdomen, staggering gait, spasm, twitching, difficulty in breathing, eyelids stuck together and reduced discharge of faeces. There were no mortalities in these groups.

Genotoxic Effects: The test substance did not lead to any increase in the rate of micronuclei. The number of normochromatic (NCE) or polychromatic (PCE) erythrocytes containing small nuclei did not deviate from the vehicle control. The decrease in ratio of PCE/NCE in the treated groups (group II, III, IV) was considered to be biologically relevant (44-70%) indicating that the test substance was toxic to the bone marrow.

Results from the vehicle and positive control demonstrated that the test method was operating satisfactorily.

Remarks - Results: The decrease in the PCE/NCE ratio confirmed that the test substance reached the bone marrow.

CONCLUSION

The notified chemical was not clastogenic under the conditions of this in vivo erythrocyte micronucleus test.

TEST FACILITY

Bayer (1992g)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry
Inoculum	Activated sewage sludge
Exposure Period	28 days
Remarks - Method	The biodegradation of the notified chemical (100 mg/L) was determined by the measurement of oxygen uptake after the medium was inoculated with a mixed population of aquatic microorganisms and stored in the dark at 20 ± 1°C for 28 days. Aniline was used as the standard material. Tests conducted in compliance with the OECD principles of GLP.

RESULTS

Test substance		*Aniline*	
Day	*% degradation*	*Day*	*% degradation*
2	4		
8	6		
14	8		
20	10		
26	12		
28	13	28	83

Remarks - Results	The results indicated that 13% of the notified chemical had degraded, while 83% of the standard degraded in 28 days.
CONCLUSION	The results indicate that the notified chemical is not ready biodegradable.
TEST FACILITY	Bayer AG (1998b)

8.1.2. Bioaccumulation

The bioaccumulation potential was not determined. The substance is not expected to be persistent in the environment on the basis that it showed some degree of biodegradability (13% in 28 days). Furthermore, the ester groups are prone to hydrolysis (refer to hydrolysis as function of pH test). Thus, while the notified chemical has a calculated Log Pow at 20°C = 6.4, when the esters are hydrolysed, the chemical would be less lipophilic and not expected to bioaccumulate, particularly given the expected low aquatic exposure.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test 96 hour, semi static.
Species	Zebra fish (*Brachydanio rerio* HAMILTON BUCHANAN)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	244 ppm $CaCO_3$ (13.7 °dH)
Analytical Monitoring	
Remarks – Method	Test conducted in compliance with the OECD principles of GLP.
RESULTS	To produce the test concentrations the test substance was weighed daily

into water and treated with an ultra-turrax for 60 seconds at 8000 rpm.
At all concentrations, some of the test substance remained undissolved on the surface of the test media. At concentrations of 100 mg/l and 316 mg/l, undissolved particles were evenly distributed in the test media.
Considering all test concentrations involved, temperature fluctuation was higher than 1ºC in the course of the study.

The amounts of water soluble test substance determined by analysis were considerably below the nominal concentrations, even at test start. The detection limit of the analytical method was 0.2 mg/L. Water quality measurements (temperature, pH and dissolved oxygen) were conducted throughout the study and were within acceptable ranges.

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*2 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	<0.2	10	0	0	0	0	0
1.0	0.7	10	0	0	0	0	0
3.2	2.2	10	0	0	0	0	0
10	7.9	10	0	0	0	0	0
31.6	24	10	0	0	0	0	0
100	72	10	0	0	0	0	0
316	231	10	0	3	10		

LC50	72-231 mg/L at 48 hours (Mean measured values)
NOEC	72 mg/L at 96 hours (Mean measured value)
Remarks – Results	The report contains an LC50 value calculated using probit analysis. The origin of the data used to calculate this endpoint is uncertain and therefore, the endpoint is not considered reliable and will not be used. The concentration of the test material was measured in the fresh solution and after 24 h. In all cases the concentration reduced with time. Mortality was only observed in the highest test concentration. Sublethal effects including abnormal swimming action, sluggishness and lethargic swimming action were observed in all 7 surviving fish at the highest test concentration after 24 h.
CONCLUSION	The notified chemical is slightly to very slightly toxic to *Brachydanio rerio* (Mensink *et al.* 1995)
TEST FACILITY	Bayer AG (1998b)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	"Bestimmung der Schwimmunfärhigkeit beim Wasserfloh – Daphnia magna " (EC 0, EC 50, EC 100; 24 Stunden; statisches System) Umweltbundesamt Berlin, May 1984. "Determination of the swimming ability with the water flea - Daphnia magna" (EC 0, EC 50, EC 100; 24 hours; static system) Federal Office for Environment Protection Berlin, May 1984.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	269 ppm $CaCO_3$ (15.1 °dH)
Analytical Monitoring	Method not specified
Remarks – Method	To produce the test concentrations the test substance was weighed into water and treated with an ultra-turrax for 60 seconds at 8000 rpm and

was then stirred for 3 hours on a magnetic stirrer. No comment on the dissolution of the test substance was made. Given the observations in the fish study it is expected that not all of the test material was dissolved.

Water quality measurements (temperature, pH and dissolved oxygen) were conducted throughout the study and were within acceptable ranges. No analysis of the test concentrations was performed.

Test conducted in compliance with the OECD principles of GLP.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
3.2	-	10	0	0
10.0	-	10	0	0
31.6	-	10	0	5
100	-	10	0	10
316	-	10	2	17
1000	-	10	20	-

EC50 88.6 (57-135 95% CI) mg/L at 48 hours
NOEC 10 mg/L at 48 hours
Remarks – Results The test results refer to nominal concentrations. As noted above considerable loss of concentration may be expected. Potassium dichromate was used as a reference toxicant for which an EC50 of 3.0 mg/L.

CONCLUSION The notified chemical is slightly toxic to *Daphnia magna* (Mensink *et al.* 1995).

TEST FACILITY Bayer AG (1998b)

8.2.3. Algal growth inhibition test

Not determined.

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical

METHOD ISO Directive 8192-1986 (E)
Inoculum Activated sludge from laboratory sewage plant
Exposure Period 3 hours
Concentration Range 1,000 - 10,000 mg/L
Nominal
Remarks – Method

RESULTS

Test concentration [mg/L]	*Respiratory rate [mg/L.h]*	*Inhibition [%]*
1000	25.5	19.0
1800	22.8	27.6
3200	19.5	38.1
5600	9.6	69.5
10000	0.0	100.0

EC50 3110 mg/L

NOEC	
Remarks – Results	The validity of the test was checked by means of a graphic evaluation of the reference substance details were not provided in report. The test substance was not totally soluble in water at a concentration of ≥ 10,000 mg/L.
CONCLUSION	The notified chemical may be considered very slightly toxic to sewage treatment bacteria.
TEST FACILITY	Bayer AG (1998b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Paint Manufacture

None of the notified chemical will be released directly to water bodies. Up to 1000 kg of waste notified chemical will be generated each year due to the formulation and use of paints containing the notified chemical. Most of this will go to landfill sites across Australia, with a small proportion incinerated during container recycling. The majority of the waste notified chemical will have reacted with the other components to form an inert matrix before reaching landfill. In landfill the notified chemical is not likely to be mobile.

Automotive

The majority of the notified chemical will be combined with other paint components to form a very high molecular weight and stable paint film. As the coating degrades over time, any fragments, chips and flakes of the lacquer will be of little concern as they are expected to be inert. The surfaces coated with the chemical are likely to be either recycled for metal reclamation or be placed into landfill at the end of their useful life (5-20 years). When recycled the chemical would be destroyed in furnaces and converted to water vapour and oxides of carbon and nitrogen.

Floor Coating Application

The chemical floor finish will cure to form an inert coating on the surface of the floors. It will remain on the floors until it is gradually worn down by human traffic, being slowly dispersed on shoes etc. At the end of its useful life it will be removed by the professional floor sanders and presumably replaced by another coat of a similar product. The coating containing the notified chemical will be broken up into solid particulate matter in the sanding/removal process and most likely disposed to landfill.

Maintenance Applications (metal or concrete substrates)

The majority of the notified chemical will be incorporated into paints that will be applied to surfaces and cured in an inert matrix. The chemical will share the fate of the surfaces to which it has been applied at the end of their useful life. Hence, it will either be disposed of to landfill or destroyed by incineration during recycling of metal surfaces.

The notified chemical is not expected to cross biological membranes, due to its susceptibility to hydrolysis and expected low environmental release, and as such should not bioaccumulate (Connell 1989).

9.1.2. Environment – effects assessment

The notified chemical is slightly to very slightly toxic to fish, daphnia and microorganisms. As only two toxicity endpoints are available a PNEC of 88.6 µg/L has been determined from the endpoint for the most sensitive organism (daphnia) and applying an assessment factor of 1000.

9.1.3. Environment – risk characterisation

Given the low aquatic exposure the determination of a predicted environmental concentration (PEC) is not possible.

Waste notified chemical from manufacture, formulation into coatings or residues in containers (either notified chemical transport drums or paint tins) will be disposed of to landfill as an inert solid where it is expected to be immobile.

The majority of waste chemical generated during application (through spills and washing) will either be disposed of in landfill or incinerated. In landfill, it is expected that the chemical may hydrolyse and slowly degrade. Incineration of the notified chemical would destroy the material with the production of water vapour, and oxides of carbon and nitrogen.

The lack of exposure of the notified chemical to the aquatic compartment indicates that the notified chemical is unlikely to have an adverse effect on aquatic organisms.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Paint Formulation

Although workers at the paint formulation site have the potential to be exposed to the notified chemical, exposure is expected to be minimal due to the use of engineering controls and PPE. Exposure is considered to be greatest for workers handling 100% notified chemical (i.e. when charging the mixer). The estimated dermal exposure is 42 mg based on EASE model (EASE) using reasonable worst-case defaults for the manual addition of liquids (European Commission, 2003) and assuming intermittent exposure. Therefore, for a 70 kg worker and a 10% dermal absorption factor (based on the high molecular weight and log P_{ow} > 4), systemic exposure is estimated to be 0.06 mg/kg bw/day. Exposure would be further limited by the use of PPE.

Automotive Application

Dermal exposure to the notified chemical during the opening of containers, mixing and connecting and unconnecting pumping equipment is expected to be low due to the low concentration of the notified chemical (< 6%) and the use of PPE. Exposure to the notified chemical is not expected during application as the spraying operation takes place within an automated, enclosed spray booth. Once the paint has dried, the notified chemical will be bound within an inert matrix and as such exposure is expected to be negligible.

Floor Coating Application

Professional flooring workers may be exposed to the notified chemical at a concentration of < 65% during opening of containers and mixing and applying of the paint, although the greatest exposure is considered to be during application. The estimated reasonable worst-case and typical case dermal exposure is 5500 mg and 935 mg respectively using measured data for the exposure scenario 'brushing and rolling of liquids' (European Commission, 2003) and assuming the notified chemical is present at a concentration of 55%. Therefore, for a 70 kg worker and a 10% dermal absorption factor (based on the high molecular weight and log P_{ow} > 4), reasonable worst-case and typical case dermal exposure is estimated to be 7.8 mg/kg bw/day and 1.3 mg/kg bw/day respectively. Exposure would be further limited by the use of PPE.

Maintenance Application

As with floor coating application, the greatest potential for exposure is considered to be during application, with reasonable worst-case and typical case dermal exposure with application by rollers or brushes estimated to be 7.8 mg/kg bw/day and 1.3 mg/kg bw/day respectively. For spray application the estimated reasonable worst-case and typical case dermal exposure is 5500 mg and 1375 mg respectively using measured data for the exposure scenario 'spray painting (large areas)' (European Commission, 2003) and assuming the notified chemical is present at a concentration of 55%. Therefore, for a 70 kg worker and a 10% dermal absorption factor (based on the high molecular weight and log P_{ow} > 4), reasonable worst-case and typical case dermal exposure is estimated to be 7.8 mg/kg bw/day and 2.0 mg/kg bw/day respectively. Inhalation exposure to the notified chemical could also occur during spray application. No monitoring data was available for paints containing the notified chemical for similar applications to that expected for the notified chemical. Monitoring data was available for another non-volatile component of paint (polyisocyanate) during the spraying of a bridge superstructure and deck (Mobay, 1989). Based on this data the airborne concentration of the notified chemical can be estimated assuming that the ratio of the notified chemical/polyisocyanate in the paint mists equals the ratio of the notified chemical/polyisocyanate in the total paint (55/5.7) and that the solids content of the paints will be similar.

Sample Site	*Measured Airborne Concentration (mg/m^3) polyisocyanate*	*Estimated Airborne Concentration (mg/m^3) notified chemical*
Painter #1	2.5	24
Painter #2	2.2	21
Painter #3	5.2	50
Downwind 50 ft	< 0.02	< 0.2
Deck	0.9	8.7

Under Bridge	0.02	0.2

Therefore for a 70 kg worker, an inhalation rate of 1.3 m^3/hour, and an 8 hour exposure time, exposure to the notified chemical for a painter is estimated to be 3.1-7.4 mg/kg bw/day. Inhalation exposure would be limited by the use of respiratory protection. Class 'M' disposable mask effectively reduce exposure by ten-fold. Powered air-purified respirators provide approximately 100-fold reduction in exposure.

9.2.2. Public health – exposure assessment

Although the public will come into contact with articles or surfaces which have been treated with paint containing the notified chemical, the notified chemical will be bound within an inert matrix and as such public exposure is expected to be negligible.

Where paint is applied by spray in an outdoor area, inhalation exposure to the notified chemical cannot be ruled out. However, measures such as physical barriers or a designated exclusion zone should limit the potential for public exposure.

9.2.3. Human health – effects assessment

Toxicokinetics, metabolism and distribution.
No information is available regarding the toxicokinetics of the notified chemical. Based on the molecular weight and high log Pow, absorption is considered to be < 10% (European Commission, 2003).

Acute toxicity.
The notified chemical is considered to be of low acute toxicity via the oral, dermal and inhalation routes.

Irritation and Sensitisation.
The notified chemical is considered to be a slight skin and eye irritant and mild respiratory irritant. The notified chemical is considered to be a skin sensitiser. As skin reactions were observed in 85% of animals at a concentration of 50%, the notified chemical is considered to be a strong sensitiser. The potential for respiratory sensitisation cannot be ruled out.

Repeated Dose Toxicity.
In a 28 day study in rats, the No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day based on the absence of adverse treatment related effects.

Mutagenicity.
The notified chemical was negative in an Ames test and an *in vivo* erythrocyte micronucleus test. The notified chemical is not considered to be mutagenic.

Neurotoxicity
In the *in vivo* mouse erythrocyte micronucleus test, following intraperitoneal administration of a fairly high dose (5345 mg/kg bw) some evidence of non-specific neurological impairment was seen. However, this was not observed in any of the tests conducted on any other species and could either be species-specific or an expression of generalised toxicity induced at high doses, as opposed to specific neurotoxicity.

Observations on Human Exposure.
The notified chemical is currently being used overseas in paint formulations, although the similarity of the overseas applications to the proposed applications is not known. The notifier stated that they have not received any incident reports that would associate the notified chemical with any adverse health effects.

Hazard classification for health effects.
Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). The classification and labelling details are:

R43 May cause sensitisation by skin contact.

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is a slight skin and eye irritant, mild respiratory irritant and potential skin and respiratory sensitiser.

The notified chemical is a C1 combustible liquid and Desmophen NH 1521 is a flammable liquid, and so should be handled and stored accordingly.

Paint Formulation
Reasonable worst-case exposure for workers involved in paint formulation is estimated to be 0.06 mg/kg bw/day. Based on a NOAEL of 1000 mg/kg bw/day, derived from a 28-day rat oral study, the margin of exposure (MOE) is calculated as 16700. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for formulation workers. The risk of irritant effects to the skin and eyes and the potential for skin sensitisation would be reduced by the use of coveralls, protective eyewear and impervious gloves. As inhalation exposure to the notified chemical is not expected, the risk of respiratory irritant or sensitisation effects is considered to be low.

Automotive Application
As exposure to the notified chemical during the preparation of the paint is considered to be less than during paint formulation, the risk of systemic effects is considered to be low. Due to the low concentration of the notified chemical (< 6%) in the automotive paint, the risk of irritant effects is considered to be low, although the risk of sensitisation cannot be ruled out. This risk would be reduced by the use of coveralls, protective eyewear and impervious gloves. As exposure to the notified chemical is not expected during application because the spraying operation takes place within an automated, enclosed spray booth, the risk to workers during application is considered to be low.

Floor Coating Application
Reasonable worst-case exposure for workers involved in floor coating application is estimated to be 7.8 mg/kg bw/day. Based on a NOAEL of 1000 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 128. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data is acceptable for workers involved in floor coating application. The risk of irritant effects to the skin and eyes and the potential for skin sensitisation would be reduced by good working practices and the use of coveralls, protective eyewear and impervious gloves. As inhalation exposure to the notified chemical is not considered to be a main route of exposure, because of the low vapour pressure and application method, the risk of respiratory irritant or sensitisation effects is considered to be low, this risk would be further reduced by the use of suitable respirator. The notifier indicated that the paint containing the notified chemical will also contain isocyanates and workers will be trained to use PPE such as appropriate respirators.

Maintenance Applications (metal or concrete substrates)
As with workers involved in floor coating applications, the risk of systemic and irritant/sensitisation effects for workers involved in the application of the paint by rollers and brushes is considered acceptable provided suitable PPE is worn.

Worst-case exposure (dermal and inhalation) for workers involved in spray application is estimated to be 15.2 mg/kg bw/day. Based on a NOAEL of 1000 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as 65. This suggests that the risk of systemic effects may not be acceptable as it is and therefore workers must have appropriate skin and respiratory protection when applying the paint by spraying. The notifier

indicated that the paint containing the notified chemical will also contain isocyanates and workers will be trained to use PPE such as appropriate respirators.

The potential risk of skin and respiratory sensitisation cannot be ruled out in workers involved in spray application. While this risk would be reduced by the use of coveralls, impervious gloves, protective eyewear and a suitable respirator, the use of PPE alone in the absence of higher level of controls (such as isolation of the spray painting process or engineering controls) may not be sufficient to mitigate concerns. Therefore, it is recommended that for maintenance applications, paint containing the notified chemical is applied by roller or brush where practicable.

9.2.5. Public health – risk characterisation

Except where paint is spray applied in an outdoor area, exposure to the notified chemical is expected to be negligible and as such the risk to public health is considered to be negligible. When the spray is applied in an outdoor area the potential for inhalation exposure and risk of sensitisation effects cannot be ruled out. This risk would be reduced by the erection of physical barriers or where an appropriate exclusion zone is established around the spray operation. However, it is recommended that paint containing the notified chemical applied in an outdoor area is applied using roller or brush where practicable.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

(Xi) Irritant: R43; May cause sensitisation by skin contact

As the notified chemical is classified as a skin sensitiser and there is potential for inhalation exposure during spraying, the following classification and labelling details should also be used as a precautionary measure:

(Xn) Harmful R42; May cause sensitisation by inhalation

and

As a comparison only, the classification of notified chemical 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.

	Hazard category	***Hazard statement***
Skin sensitiser	1	May cause allergic skin reaction

10.2. Environmental risk assessment

The chemical 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

Paint Formulation, Automotive and Floor Coating Application

There is Moderate Concern to occupational health and safety under the conditions of the occupational settings described due to the potential for skin and respiratory sensitisation. This concern is reduced by the use of engineering controls and recommended PPE.

Maintenance Applications (metal or concrete substrates)

There is High Concern to occupational health and safety under the conditions of the occupational settings described due to the potential for skin and respiratory sensitisation and the lack of hierarchy of controls.

10.3.2. Public health

Automotive and Floor Coating Application

There is Negligible Concern to public health when used in the proposed manner.

Maintenance Applications (metal or concrete substrates)

There is No Significant Concern to public health when used in the proposed manner however the risk of a sensitisation response cannot be ruled out.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are 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 chemical and products containing the notified chemical provided by the notifier were 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

REGULATORY CONTROLS

Hazard Classification and Labelling

- The ASCC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R43 May cause sensitisation by skin contact.

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Conc≥1%: R43 May cause sensitisation by skin contact
  - Conc≥1%: R42 May cause sensitisation by inhalation

- The following safety phrases should appear on the MSDS and label for the notified chemical:
  - S23 Do not breathe spray
  - S24 Avoid skin contact
  - S36/37 Wear suitable protective clothing/gloves
  - S51: Use only in well-ventilated areas

Health Surveillance

- As the notified chemical is a skin sensitiser and potential respiratory sensitiser employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation. Workers who become sensitised to the notified chemical should be transferred to another workplace/not continue to handle the chemical.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced and in the formulated paint product:
  - Avoid generation of aerosols during paint formulation and preparation
  - Spray application should be carried out in an enclosed automated spray booth, except where not practicable

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and in the formulated paint product:
  - Avoid skin and eye contact
  - Avoid breathing spray
  - Use of spray paints containing the notified chemical should be accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC, 1999) or relevant State and Territory Codes of Practice.
  - Proper induction training and general training of workers about the potential hazards of spraying with paint containing the notified chemical and in the safe work practices to minimise exposure
  - Restrict access to spray painting areas
  - Care must be taken to avoid exposure to spray drift

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and in the formulated paint product:
  - Impermeable gloves;
  - Coveralls;
  - Eye protection;
  - Suitable respirators where inhalation exposure is possible

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Atmospheric monitoring should be conducted to measure workplace concentrations of the notified chemical during outdoor spray application of paint containing the notified chemical to large areas. It is recommended that this monitoring is combined with health surveillance monitoring

- The notified chemical as introduced should be handled consistent with provisions of State and Territory legislation regarding the Handling of Combustible and Flammable Liquids.

- 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.

Public Health

- The employer should implement measures to minimise public exposure to the notified chemical during outdoor spray application, including:
  - establishment of an appropriate spray paint exclusion zone
  - public access to applied areas must be restricted until the paint is completely dry
  - restriction of spraying under certain weather conditions to minimise spray drift e.g. high winds
  - conduct of spraying away from the boundary to adjacent premises or where carparks and other sensitive property is located.

Environment

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
  - Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

- Wastes generated during industrial application should be disposed of through a licensed waste contractor.

Storage

- The notified chemical as introduced should be stored consistent with provisions of State and Territory legislation regarding the Storage of Combustible and Flammable Liquids.

Emergency procedures

- Spills/release of the notified chemical should be handled by absorbing onto an inert material, scooping up and placing in marked containers for 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
  - any atmospheric monitoring data for spray application becomes available.
  - any health surveillance data for the notified chemical becomes available.

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.

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