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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Desmophen NH 1420

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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FULL PUBLIC REPORT

Desmophen NH 1420

This assessment report is for an extension of original assessment certificate for Desmophen NH 1420. Based on the submission of new information by the extension notifier, some sections of the original assessment report for Desmophen NH 1420 have been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Holders of the Original Assessment Certificate (No. 2554*, STD/1215):*
Bayer Australia Ltd (ABN 22 000 138 714)
500 Wellington Road
Mulgrave VIC 3170

and

Akzo Nobel Pty Ltd (trading as International Protective Coatings) (ABN 59 000 119 424)
115 Hyde Road
Yeronga QLD 4104

Applicant for an Extension of the Original Assessment Certificate:
Australian Urethane Systems Pty Ltd (ABN 50 000 168 874)
25 Garling Rd
Kings Park NSW 2148

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 identity (Chemical name, other names, CAS. Number, Molecular Formula, Structural Formula. Molecular weight, Spectral Data)
- Composition (Purity, identity of toxic or hazardous impurities, % weight of toxic or hazardous impurities, non-hazardous impurities, identity of additives/adjuvants, % weight of additives/adjuvants).
- Percentage of notified chemical in end-use preparations
- Import volumes
- Identity of sites
- Specific use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Physical Chemical Properties
Density
Adsorption/Desorption
Explosive properties
Acute Toxicity
(a) Acute Oral Toxicity
(b) Acute Dermal Toxicity
(c) Acute Inhalation Toxicity
(d) Skin Irritation
(e) Eye Irritation
(f) Skin Sensitisation
(g) Repeated Dose Toxicity
Genetic Toxicity

(h) Induction of Point Mutations
(i) Chromosome Damage
Ecotoxicity
(j) Fish, Acute Toxicity
(k) Daphnia sp., Acute Immobilisation/Reproduction
(l) Alga, Growth Inhibition Test
Biodegradation
(m) Ready Biodegradation
(n) Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2000)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Desmophen NH 1420

Extension Application:
Polycoat Staingard 6000 Clear – Part B (product containing 40-52 % Desmophen NH 1420)
Polycoat Staingard 6072 Clear – Part B (product containing 30-40% Desmophen NH 1420)

METHODS OF DETECTION AND DETERMINATION

METHOD	UV/VIS, IR and NMR spectroscopy
Remarks	Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90 %

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 finished product at a concentration of 20-60%. However in the future, based on performance in the first year, it is envisaged the Desmophen NH 1420 will be imported neat for formulation into final products in Australia.

Following import the notified chemical in the finished product will be transported by road to the notifier's warehouse for storage before being on-sold to customers. In the future the notified chemical will be stored at Akzo Nobel's warehouse and formulated into finished products to be sold to various industries.

Extension Application:
The notifier will import formulated two-part coating systems (Stainguard 6000, Stainguard 6072) and will not be importing the notified chemical as such. These products may be manufactured locally in Australia in the future, however it is unlikely that this would happen within the next five years.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 300	< 300	< 300	< 300	< 300
Extension Application:					
Year	*1*	*2*	*3*	*4*	*5*
Tonnes	4	8	10	12	12

USE
Amino functional reactive thinner for low VOC, one or two component polyurethane/urea paint systems for maintenance, automotive and light industrial applications.

Extension Application:
The notified chemical is an ingredient in industrial surface coatings for steel and concrete surfaces in industrial settings.

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.

Extension Application:
Sydney, NSW

IDENTITY OF MANUFACTURER/RECIPIENTS
Paint manufacturers.

Extension Application:
Australian Urethane Systems Pty Ltd
25 Garling Rd
Kings Park NSW 2148

TRANSPORTATION AND PACKAGING
Desmophen NH 1420 will be imported in 205 L sealed closed head steel drums and transported by road from wharf to storage facility.

Extension Application:
The products containing the notified chemical will be imported in 18.9 L steel pails. These pails will be delivered from the wharf to the notifier's warehouse for unpacking and storage. The pails will then be dispatched by road to various applicator customers around Australia.

5.2. Operation description

Truck drivers will transport the sealed containers by road from the wharf to the notifier's contract warehouse and then as needed to the customer(s) warehouse. Two incoming goods receiving personnel will unload the containers using a forklift and store them in designated storage areas.

The chemical will be reformulated into paint products at the customer's paint manufacturing site. Formulation of the notified chemical into paint products will involve manual transfer of notified chemical using drum hoist and pouring directly into the mixing vessel or by metered dosing using metering pump to mixing vessel and mixing the notified chemical and other ingredients in a sealed vessel fitted with a high-speed mixer and local exhaust ventilation system. Each batch is to be quality checked and adjustments made as required. The resultant paint is filtered prior to being dispensed into 4 L, 10 L and 20 L cans under exhaust ventilation for supply to customers. The final concentration of the notified chemical in the final product will be 20-60%. 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 user's site, the 4 L, 10 L and 20 L steel cans will be opened under local fume extraction. If required, the second component of the 2-pack system will be added at a 5:1 to 2:1 ratio (resulting in a notified chemical concentration of 13 - 60%, respectively) to the same container and the contents stirred using a mechanical stirring paddle at a slow speed following which 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 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 4 L, 10 L and 20 L pails containing the floor coating. If required, they will add the second component of the 2-pack system at a 5:1 to 2:1 ratio (resulting in a notified chemical concentration of 13 - 60%) 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)
Coatings containing the notified chemical (at 20 - 60%) may be applied to metal or concrete structures such as bridges and buildings. The method of application will mostly involve the use of brushes, rollers, and spray painting of new steel. Professional tradesman will open 4 L, 10 L and 20 L pails of paint, if required, add the second component of the 2-pack system at a 5:1 to 2:1 ratio (resulting in a notified chemical concentration of 13 - 60%, respectively) 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 or metal structures using a paint brush or roller. For spray painting, the mixed paint will be manually poured into a 5 L spray gun reservoir and used.

Extension Application:
As extension applicant will only import formulated paint/coating systems, blending will not be performed in Australia.

The product containing the notified chemical will be mixed with the other part of the coating product in a 1:1 ratio. The coating mixture will be applied to steel or concrete surfaces using a notched trowel, squeegee or an adhesive phenolic resin core roller. Typical structures coated are tanks, bridges and other industrial plant.

5.3. Occupational exposure

Number and Category of Workers

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

Exposure Details
Transport and storage
Exposure to the notified chemical is unlikely during transportation and storage. Exposure may result in case of an accidental spill or leak in the pails or drums. No specific precautions are required. Gloves, coveralls and goggles are available if required.

Paint formulation
Paint make up – Workers may be exposed to notified chemical via dermal and ocular exposure due to spills and leaks, during charging of the mixer and blending. Workers will wear coveralls, goggles and impervious gloves. Aerosols may be released during blending, but inhalation exposure is likely to be low due to the local exhaust ventilation system and the closure of the system if high speed stirring

occurs. Where ventilation is inadequate a respirator will be worn.

QC testing
Dermal and ocular exposure to drips, spills and splashes is possible 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 to control exposure.

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

Automotive Application
Potential worker exposure to the paint containing the notified chemical will mostly occur during opening of containers, mixing and connecting and disconnecting 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.

Extension application:
As formulated paint/coating systems will be imported under the extension application, exposure may occur during transport, storage and end-use application to metal and steel substrates

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia. Desmophen NH 1420 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 the 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 of to landfill.

During reformulation into automotive and floor coatings, residual material in empty drums is estimated to account for ≤1% of import volume. The empty drums will be disposed of to landfill by a waste contractor. Spills and leaks and washings from process equipment are expected to account for a further ≤1% of import volume. 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. 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. The filters are collected periodically and disposed of to landfill.

Floor Coatings
Residual notified chemical in the empty 4 L, 10 L and 20 L containers will account for ≤2.5% of the import volume. This material will be mixed with the second part of the polyurethane coating system and once applied is allowed to cure. The cured solid material will be disposed of to landfill along with the container. Any rollers and paint brushes used 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)
Residual notified chemical in the empty 4 L, 10 L and 20 L containers will account for ≤1.5% of the import volume. This material will be mixed with the second part of the polyurethane coating system and once applied is 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 used 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 ≤20% of the paint volume. This is estimated to equate to ≤4% of the import volume (based on 20% 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 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 off to landfill. Solvent washings may be incinerated.

Paint Manufacture
Waste generated during the manufacture of paint will account for approximately 2% of the total annual import volume of notified chemical. This is likely to be disposed of to landfill but some may be incinerated.

Automotive
Waste generated during the application of paint is expected to account for approximately 10% of the total annual import volume of notified chemical. This is expected to be disposed of to landfill across Australia. Residues in paint containers will either be disposed of to landfill or incinerated in container recycling, accounting for up to 0.1 % of the total annual import volume.

Floor Coatings
Residues in empty paint containers is expected to account for approximately 0.5% of the total annual import volume, and will be disposed of to landfill in cured form. 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 of to landfill.

Maintenance Applications (metal or concrete substrates)
Residues in empty paint containers is expected to account for approximately 0.5% of the total annual import volume, and will be disposed of to landfill in cured form. 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.

Extension Application:
The formulated products containing the notified chemical will not be sold to the public. As the products will only be used on industrial sites such as tankage, bridges, mining and sewerage plants etc, the general public should not come in contact with the notified chemical. The public may come into contact with cured coatings, where the notified chemical is not bioavailabe.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Light yellow liquid

Pour Point Approx. -17°C

METHOD ASTM Method D 9787 (Standard Test method for the pour point of Petroleum Oils)
Remarks Summary was provided.

Boiling Point 234°C at 101.3 kPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Photocell detection

Density Approx. 1061.9 kg/m^3 at 20 °C

Remarks Analogue chemical data (Desmophen 1521, 90% solution of the analogue chemical in n-butyl acetate).

Vapour Pressure 1.79×10^{-6} kPa 20 °C
2.61×10^{-6} kPa 25 °C
1.20×10^{-5} kPa 50 °C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Using a vapour pressure balance

Water Solubility 0.0737 g/L 20°C

METHOD OECD TG 105 Water Solubility.
Remarks Flask shaking method. 1 g stirred in 100 mL. After centrifugation and freeze-drying, residues were analysed using SFC (Chromatography with supercritical CO_2). The results of the SFC analysis of the residues showed evidence of reaction with water.
TEST FACILITY Bayer AG (1994)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

pH	*t½ (hours)*
4	920
7	27.4
9	29.0

Remarks The hydrolysis products have not been characterised experimentally, however, hydrolysis is most likely to occur at the carboxylic ester linkages to generate unesterified notified chemical and the respective alcohols.
TEST FACILITY Not specified.

Partition Coefficient (n-octanol/water) log Pow = 5.4 at 20ºC (estimated)

METHOD Estimated using the Clog P program.
Remarks Neither HPLC nor Shake/Flask method were found to be suitable.
TEST FACILITY Bayer AG (1994)

Adsorption/Desorption Not determined

Remarks The log K_{OC} was calculated using the log P_{OW} using ACD software. The notified chemical is expected to bind strongly to organic matter in soil.

Dissociation Constant pKa = ~ 7.32 and ~ 6.72

METHOD ACD/pKa Predictor 2.7
Remarks

Group	*Acid/Base*	*pKa*	*Charged at pH (?)*		
			< 6.5	*7*	*> 7.5*
One amine N	Weak base	7.32	Yes	Yes	Yes
Other amine N	Weak base	6.72	Yes	No	No

At neutral pH (pH 7) one amine nitrogen is expected to carry a cationic charge. At slightly acid pH, both amine nitrogens will be charged and at slightly basic pH, neither amine nitrogen will be charged.
TEST FACILITY CanTox Inc

Particle Size Not applicable as it is a liquid.

Flash Point 100 ºC at 101.1-101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Bayer Standard Operating Procedure for the determination of Flash-point.
Remarks DIN 51578. The notified chemical is classified as a C1 combustible liquid (NOHSC, 2001)
TEST FACILITY Bayer AG (1994)

Flammability Limits The notified chemical has no pyrophoric properties (spontaneous flammability) at room temperature

METHOD EC Directive 92/69/EEC A.13 Pyrophoric properties of solids and liquids.
Remarks Based on the presence of other ingredients finished products containing Desmophen NH 1420 are classified as flammable according to the Australian Dangerous Goods classification (FORS, 1998).
TEST FACILITY Bayer AG (1994)

Autoignition Temperature Approx. 365ºC

METHOD Not specified
Remarks Cited in MSDS for Desmophen 1420

Explosive Properties Not explosive

METHOD A.14 EEC Directive 84/449 Explosive Properties.
Remarks Explosive potential of the analogue chemical (Desmophen 1520) 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 (1991)

Reactivity

Remarks May form carbon monoxide, carbon dioxide and other toxic gases during thermal

decomposition.

Viscosity 1450 mPas at 25°C

METHOD DIN EN ISO 3219/A.3
Remarks Cited in MSDS for Desmophen NH 1420

7. TOXICOLOGICAL INVESTIGATIONS

Toxicological data were provided for Desmophen NH 1520, a close analogue.

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 vivo erythrocyte micronucleus test	non clastogenic

7.1. Acute toxicity – oral

TEST SUBSTANCE Analogue 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 analogue chemical is of low toxicity via the oral route.

TEST FACILITY Bayer (1990)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Analogue 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 analogue chemical is of low toxicity via the dermal route.

TEST FACILITY Bayer (1992d)

7.3. Acute toxicity – inhalation

TEST SUBSTANCE Analogue 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 analogue chemical is of low toxicity via inhalation. The analogue chemical is a mild respiratory tract irritant.
TEST FACILITY	Bayer (1998a)

7.4. Irritation – skin

TEST SUBSTANCE	Analogue 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 analogue chemical is slightly to moderately irritating to the skin.
TEST FACILITY	Bayer (1991e)

7.5. Irritation – eye

TEST SUBSTANCE	Analogue 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 analogue chemical is slightly irritating to the eye.

TEST FACILITY Bayer (1991e)

7.6. Skin sensitisation

TEST SUBSTANCE Analogue 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 analogue chemical under the conditions of the test.

TEST FACILITY: Bayer (1992e)

7.7. Repeat dose toxicity

TEST SUBSTANCE: Analogue 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	Analogue 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 analogue chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Bayer (1991f)

7.9. Genotoxicity – in vivo

TEST SUBSTANCE	Analogue 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 analogue 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 analogue 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 analogue chemical was not clastogenic under the conditions of this in vivo erythrocyte micronucleus test.
TEST FACILITY	Bayer (1992g)

8. ENVIRONMENT

Environmental fate and ecotoxicological data were provided for Desmophen NH 1520, an acceptable analogue.

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry
Inoculum	Activated sewage sludge
Exposure Period	28 days
Remarks - Method	The biodegradation of the test substance (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 ± 1ºC for 28 days. Aniline was used as the standard material.

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 test substance had degraded, while 83% of the standard degraded in 28 days.

CONCLUSION The results indicate that the test substance 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 the analogue chemical 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 test substance has a calculated Log Pow at 20°C = 6.55, 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 Analogue chemical

METHOD
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

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 the 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 test substance 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	Analogue chemical (purity 91.6%)
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.

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 test substance 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 Analogue chemical

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

RESULTS
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

Test concentration [mg/L] [mg/L.h]	*Inhibition [%]*	*Respiratory rate*
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

CONCLUSION The test substance 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 7% of the total annual import volume 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 either be disposed of to landfill or destroyed by incineration during recycling of metal surfaces.

The 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 1990).

9.1.2. Environment – effects assessment

The acceptable analogue 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 chemical from manufacture, formulation into coatings or residues in containers (either 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 chemical would destroy the material with the production of water vapour, and oxides of carbon and nitrogen.

The lack of exposure of the chemical to the aquatic compartment indicates that the 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 disconnecting pumping equipment is expected to be low due to the use of engineering controls and 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 < 60% 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 6000 mg and 1020 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 60%. 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 8.6 mg/kg bw/day and 1.46 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 8.6 mg/kg bw/day and 1.46 mg/kg bw/day respectively. For spray application the estimated reasonable worst-case and typical case dermal exposure is 6000 mg and 1500 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 60%. 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 8.6 mg/kg bw/day and 2.14 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 were available for another non-volatile component of paint (polyisocyanate) during the spraying of a bridge superstructure and deck (Mobay, 1989). Based on these 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 (60/5.7) and that the solids content of the paints will be similar.

Sample Site	*Measured Airborne Concentration (mg/m³) polyisocyanate* *Estimated Airborne Concentration (mg/m³) notified chemical*
Painter #1	2.5 26
Painter #2	2.2 23
Painter #3	5.2 55
Downwind 50 ft	< 0.02 < 0.21
Deck	0.9 9.5
Under Bridge	0.02 0.21

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 3.4-8.1 mg/kg bw/day. Inhalation exposure would be limited by the use of respiratory protection. Class 'M' disposable masks 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 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 analogue 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 finished products containing Desmophen NH 1420 are flammable liquids, 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. The risk of irritant effects and the risk of sensitisation cannot be ruled out due to the concentration of the notified chemical (< 60%) in the automotive paint. 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 8.6 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 117. 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 16.7 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 60. 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. Risk assessment relating to extension application

The use and the fate of the notified chemical under the proposed extension is within the range of scenarios covered by the original assessment. The increase in proposed introduction volume is not expected to significantly change the environment and health impacts. Therefore, there are no changes required in the risk assessment. It is noted that spray application will not occur under the extension application.

11. CONCLUSIONS AND REGULATORY OBLIGATIONS

11.1. 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

11.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

11.3. Human health risk assessment

11.3.1. 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.

Extension 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 recommended PPE.

11.3.2. 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.

12. MATERIAL SAFETY DATA SHEET

12.1. 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.

Extension Application:
The applicant for extension application has provided MSDSs of products containing the notified polymer. The accuracy of the information on the MSDSs remains the responsibility of the extension applicant.

12.2. 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.

13. 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 car parks 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.

13.1. 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/analogue 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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