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

PUBLIC REPORT

Polymer in Durazane 1500

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, 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 Energy.

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**Director
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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1635	Merck Pty Ltd	Polymer in Durazane 1500	Yes	< 100 tonnes per annum	Component of industrial coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table:

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute toxicity, oral (Category 3)	H301 – Toxic if swallowed
Skin corrosion/irritation (Category 1B)	H314 – Causes severe skin burns and eye damage

Human health risk assessment

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
 - Acute toxicity, oral (Category 3): H301 – Toxic if swallowed
 - Skin corrosion/irritation (Category 1B): H314 – Causes severe skin burns and eye damage

The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present and the intended use/exposure scenario.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation and end use:
 - Enclosed, automated system where possible
 - Sufficient ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation and end use:
 - Avoid contact with skin and eyes
 - Avoid inhalation of vapours and aerosols
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation and end use:
 - Protective clothing
 - Impervious gloves
 - Safety glasses
 - Respiratory protection if inhalation exposure may occur

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice. Atmospheric monitoring on ammonia and ethanol should be conducted to measure workplace concentrations during handling the notified polymer in contact with moisture.
- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

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

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - additional information becomes available on the (eco)toxicity of the notified polymer;or
- (2) Under Section 64(2) of the Act; if

- the function or use of the polymer has changed from a component of industrial coatings, or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Safety Data Sheet

The SDSs of products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Merck Pty Ltd (ABN: 80 001 239 818)
Ground Floor, Building 1
885 Mountain Highway
BAYSWATER VIC 3153

NOTIFICATION CATEGORY

Standard: Synthetic polymer with Mn < 1,000 g/mol (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 and structural formulae, molecular weight, analytical data, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical and (eco)toxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Permit

NOTIFICATION IN OTHER COUNTRIES

China

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Durazane 1500 (products individually containing > 60% notified polymer)

MOLECULAR WEIGHT

Number average molecular weight (Mn) < 500 g/mol

ANALYTICAL DATA

Reference GPC and FTIR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 99 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless to slightly yellow liquid*

Property	Value	Data Source/Justification
Freezing Point*	approximately -58 °C	Measured
Boiling Point	356.88 °C	Calculated (MPBVP v1.43; US EPA 2017)
Density*	967 kg/m ³	SDS
Vapour Pressure	1.21 × 10 ⁻⁵ kPa at 25°C	Calculated (MPBVP v1.43; US EPA 2017)
Water Solubility	Cannot be determined	The notified polymer is hydrolytically unstable.
Hydrolysis as a Function of pH*	t _{1/2} < 30 minutes at pH 4 and pH 9 at 50°C	Measured
Partition Coefficient	Cannot be determined	The notified polymer is hydrolytically

(n-octanol/water)		unstable.
Adsorption/Desorption	Cannot be determined	The notified polymer is hydrolytically unstable.
Dissociation Constant	Cannot be determined	The notified polymer is hydrolytically unstable.
Flash Point*	16 - 20 °C at 101.3 kPa	Measured
Flammability	Upper limit: 16.3 % Lower: 0.8 %	Estimated
Auto ignition Temperature	380 °C at 101.3 kPa	Estimated
Explosive Properties	Predicted negative	Based on the structure and oxygen balance of the notified polymer
Oxidising Properties	Predicted negative	Based on the structure of the notified polymer

* Properties of the imported products Durazane 1500

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties for melting/freezing point, hydrolysis and flash point refer to Appendix A.

Reactivity

The notified polymer rapidly hydrolyses in contact with water to form cross-linked polymers (with significantly increased molecular weight) and liberate ethanol, hydrogen and ammonia.

Physical hazard classification

As limited data on the notified polymer were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

The notifier has classified each of the Durazane 1500 products containing the notified polymer at > 60 % in the provided SDSs as follows:

<i>Hazard classification</i>	<i>Hazard statement</i>
Flammable Liquids (Category 2)	H225 – Highly flammable liquid and vapour

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. It will be imported into Australia as a component of products Durazane 1500 at > 60% concentration for reformulation into coatings.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	< 100	< 100	< 100	< 100	< 100

PORT OF ENTRY

Sydney and Melbourne

IDENTITY OF MANUFACTURER

Manufacturer: Merck KGaA (Germany)

Recipient: Merck Pty Ltd

TRANSPORTATION AND STORAGE

The notified polymer will be imported at > 60 % concentration in a variety of pack sizes and transported on pallets. Following reformulation, the finished coating products containing the notified polymer at ≤ 80 % concentration will be packed in a variety of pack sizes and transported on pallets. The imported formulations and finished products will be stored in cool, dry, well ventilated areas away from any source of ignition, heat or light.

USE

The notified polymer will be used as a component of industrial coatings at ≤ 80 % concentration. The coatings will be applied to a variety of substrates including metals.

OPERATION DESCRIPTION*Reformulation*

The imported products containing the notified polymer at > 60 % concentration will be transferred to the mixing vessel using a spear pump where it will be blended with other ingredients in the presence of local exhaust ventilation. Following blending, samples of the finished products will be taken for quality control testing. The finished coatings containing the notified polymer at ≤ 80 % concentration will be filled into 1 – 200 L steel containers through low pressure pumps.

End-use

Coatings containing the notified polymer at $\leq 80\%$ concentration will primarily be applied in purpose-built industrial facilities by a variety of application techniques including spin coating, dip coating and spray coating. These products may also be applied by wipe coating (by hand).

6. HUMAN HEALTH IMPLICATIONS**6.1. Exposure Assessment****6.1.1. Occupational Exposure****CATEGORY OF WORKERS**

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport	4	8	10
Distribution	6	4	20
Warehousing	5-20	1	40-60
Coating production	20	3	60
Quality control	10	3	60
End-use	50	5	30

EXPOSURE DETAILS*Transport and storage*

Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident.

Reformulation

Reformulation operations are expected to be largely enclosed and automated; however, dermal and ocular exposure of workers to the notified polymer at > 60 % concentration may occur when connecting or disconnecting transfer hoses, cleaning or maintaining equipment and testing for quality control. Inhalation exposure to the notified polymer may also occur if vapours or aerosols are formed. Exposure will be further mitigated through the use of local exhaust ventilation and personal protective equipment (PPE) including coveralls, impervious gloves, safety glasses and respirators, as stated by the notifier.

End-use

Dermal, ocular and inhalation exposure to the notified polymer at $\leq 80\%$ concentration may occur during application of the finished coatings. As stated by the notifier the potential for exposure will be minimised through the use of PPE (goggles, impervious gloves, coveralls) by workers, including the use of respiratory protection during spray application. Inhalation exposure should be further mitigated through the use of local exhaust ventilation and spray booths. Furthermore, the spray booth will be monitored to ensure that the exposure standards for ethanol and ammonia (SWA, 2013) are not exceeded by the applicators. Once the coating has dried and cured, the notified polymer will be bound within an inert solid matrix and is not expected to be available for exposure.

6.1.2. Public Exposure

The notified polymer will be used for industrial and professional purposes and will not be made available to the public. The public may come into contact with substrates which have been coated with coatings containing the notified polymer. However, once the coating has dried and cured, the notified polymer will be bound within an inert solid matrix and is not expected to be available for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the imported Durazane 1500 products containing > 60 % concentration are summarised in the following table. For full details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50: 200 - 2000 mg/kg bw; harmful to toxic
Rabbit, skin irritation	severe irritating
Mutagenicity – Point mutation	non mutagenic

Toxicokinetics

Based on the low number average molecular weight (< 500 g/mol) of the notified polymer, there is potential for the polymer to cross biological membranes. However, absorption is expected to be very limited as the notified polymer undergoes rapid hydrolysis in contact with moisture to form cross-linked polymers (with significantly increased molecular weight).

Acute toxicity

No acute toxicity data on the notified polymer were submitted. A Durazane 1500 product was found to be harmful to toxic via the oral route in a study conducted in rats.

Irritation

No irritation data on the notified polymer were submitted. Based on its structure, it may have irritation properties. A Durazane 1500 product was found to be severely irritating/corrosive to the skin in a study conducted in a rabbit.

Mutagenicity

No mutagenicity data on the notified polymer were submitted. A Durazane 1500 product was negative in a bacterial reverse mutation assay.

Health hazard classification

Limited toxicity data on the notified polymer were provided.

The notifier has classified each of the Durazane 1500 products containing the notified polymer at > 60 % in the SDS provided as follows:

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute toxicity, oral (Category 3)	H301 – Toxic if swallowed
Acute toxicity, dermal (Category 5)	H313 – May be harmful in contact with skin
Acute toxicity, inhalation (Category 3)	H331 – Toxic if inhaled
Skin corrosion/irritation (Category 1B)	H314 – Causes severe skin burns and eye damage
Sensitisation, skin (Category 1)	H317 – May cause an allergic skin reaction

Based on the toxicity studies provided for the products containing > 60 % of the notified polymer, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table:

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute toxicity, oral (Category 3)	H301 – Toxic if swallowed
Skin corrosion/irritation (Category 1B)	H314 – Causes severe skin burns and eye damage

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Limited toxicological data on the notified polymer are available.

During reformulation and application of coatings containing the notified polymer, dermal, ocular and inhalation exposure of workers is expected to be limited by the use of engineering controls and PPE. Once the coating has dried and cured, the notified polymer will be bound within an inert solid matrix and is not expected to be bioavailable. Furthermore, absorption of the notified polymer is expected to be very limited as the notified polymer undergoes rapid hydrolysis in contact with moisture to form cross-linked polymers (with significantly increased molecular weight).

Therefore, given the expected low exposure under the conditions of the occupational settings and the low absorption of the notified polymer, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer will be used in industrial and professional settings only and will not be made available to the public. Members of the public may come into contact with surfaces coated with products containing the notified polymer. However, once the coating has dried and cured, the notified polymer will be bound within an inert solid matrix and is not expected to be bioavailable.

Based on the assessed use patterns, the risk to the public from use of the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The imported products containing the notified polymer will be reformulated into industrial coatings. The reformulation process will involve transferring the imported product to the mixing vessel using a spear pump, where it will be blended with other ingredients in the presence of local exhaust ventilation. The reformulated products will then be filled into end use containers through low pressure pumps. Blending equipment will be cleaned with solvents and the waste liquids containing the notified polymer will be disposed of by a licensed waste contractor. Release of the products containing the notified polymer to the environment in the event of accidental spills or leaks during reformulation, storage and transport is expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The coatings containing the notified polymer will mainly be applied in purpose-built industrial facilities by a variety of application techniques including spin coating, dip coating, spray coating and wipe coating. The majority of the coatings containing the notified polymer are expected to be cured and immobilised on the metal surface. It is expected that some of the coatings will be in the form of overspray during spraying operations, and will typically entail disposal to landfill after being collected and cured. The liquid waste from cleaning of the application equipment is expected to be collected by a licensed waste contractor, and be disposed of safely. During use, the notified polymer may also be released to the environment as accidental spills. These releases are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified polymer is expected to share the fate of the articles to which it has been applied, to be either recycled for metal reclamation or disposed of to landfill at the end of their useful life. Empty import and end use containers containing residues of notified polymer will be collected by a licensed waste contractor for safe disposal.

7.1.2. Environmental Fate

As a result of its use pattern, the majority of the notified polymer is expected to share the fate of the article to which it has been applied, to be either recycled for metal reclamation or disposed of to landfill at the end of their useful life. During metal reclamation, the notified polymer will thermally decompose to form water vapour and oxides of carbon, nitrogen and silicon. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile. Based on its rapidly hydrolysis property, the notified polymer is not expected to be bioaccumulative. In landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon, nitrogen and silicon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified polymer to the aquatic environment will be limited based on its reported use pattern.

7.2. Environmental Effects Assessment

The results from the fish acute toxicity investigation conducted on a Durazane 1500 product are summarised in the table below. Details of the study can be found in Appendix C.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	EC50 = 57.1 mg/L	Harmful to fish

As limited ecotoxicological data on the notified polymer were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS). The notifier has classified each of the Durazane 1500 products in the provided SDSs as “Acute Category 2; Toxic to aquatic life” and “Chronic Category 2: Toxic to aquatic life with long lasting effects” under the GHS (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has not been calculated since no significant release of the notified polymer to the aquatic environment is expected from the proposed use pattern.

7.3. Environmental Risk Assessment

The risk quotient ($Q = \text{PEC}/\text{PNEC}$) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern as a component of industrial coatings. On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point Approximately -58 °C

Method In house method
 Remarks Determined using a thermometer
 Test Facility Merck (2017a)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH
 EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as
 a Function of pH

<i>pH</i>	<i>T (°C)</i>	<i>t_{1/2} (minutes)</i>
4	50	< 30
9	50	< 30

Remarks The hydrolysis of the test substance was determined by the increase of the reaction product ammonia concentration over time for certain pH-values. NaOH solution was added to the samples until pH 12 was reached before ammonia was measure by ammonia ion selective electrode (as the electrode sensitivity is optimised at pH > 11).The ammonia concentration increased within the first 30 minutes very rapidly with almost no change in the next 1500 minutes. The results indicate a very fast hydrolysis starting apparently at a 1st order rate, but deviates from this as the reaction progresses. This may hint further reaction kinetics different from 1st order.

Test Facility Merck (2017b)

Flash Point 16 - 20 °C at 101.3 kPa

Method DIN EN ISO 13736
 Remarks Closed cup
 Test Facility Siemens (2007)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Durazane 1500 (> 60 % notified polymer)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/ Wistar Crl:(WI) BR
Vehicle	None
Remarks - Method	The test started at 2000 mg/kg bw which was reduced to 200 mg/kg bw (instead of 300 mg/kg bw recommended in OECD TG 423) due to mortalities in 2/3 animals.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3 F	2,000	2/3
2	3 M	200	0/3
3	3 F	200	0/3

LD50	200-2000 mg/kg bw
Signs of Toxicity	One animal was found dead and 1 animal was sacrificed due to ethical reasons within 2 hours after treatment at 2000 mg/kg bw. Lethargy, hunched posture, swelling of the abdomen, piloerection, hypothermia, slow breathing, chromodacryorrhoea and/or ptosis were noted in females treated at 2000 mg/kg bw. Lethargy and hunched posture were observed on in female animals treated at 200 mg/kg bw and lethargy was noted in male animals treated at 200 mg/ kg bw.
Effects in Organs	Macroscopic findings included thickened glandular mucosa and/or limiting ridge of the stomach and hardened contents of the stomach noted in the surviving animal treated at 2000 mg/kg bw, dark red discolouration of the glandular mucosa of the stomach, ileum and jejunum, friable contents of the stomach, small intestines distended with gas, and/or enlarged spleen noted in the animal that died and in the animal that was sacrificed for ethical reasons. No macroscopic findings were noted in other animals.
Remarks - Results	Mean body weight gain was considered by the study authors to be normal.

CONCLUSION The test substance is harmful via the oral route.

TEST FACILITY Notox (2002a)

B.2. Irritation – skin

TEST SUBSTANCE	Durazane 1500 (> 60 % notified polymer)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion
Species/Strain	Rabbit/New Zealand White
Number of Animals	1
Vehicle	None
Observation Period	1 hour
Type of Dressing	Semi-occlusive
Remarks - Method	Only 1 animal was tested. After 1 hour exposure, the study was terminated by removal of the remaining 4 hours exposure dressing due to sings of severe skin reactions noted and the animal was sacrificed for ethical reasons.

RESULTS

Lesion	Mean Score*			Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3			
Erythema/Eschar	4	0	0	4	1 hr	4
Oedema	1	0	0	4	1 hr	4

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

Remarks - Results	Slight to well-defined erythema and very slight oedema was noted on the treated skin 3 minutes after exposure. Severe erythema and very slight oedema was noted 1 hour after exposure. After removal of the dressing, wounds with serious exudates and grey discoloration of the skin was noted. The study was immediately terminated and the animal was sacrificed for ethical reasons. No signs of systemic toxicity were noted.
CONCLUSION	The test substance was classified by the study author as “causes burns”.
TEST FACILITY	Notox (2002b)

B.3. Genotoxicity – bacteria

TEST SUBSTANCE	Durazane 1500 (> 60 % notified polymer)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test Plate incorporation procedure
Species/Strain	<i>Salmonella typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>Escherichia coli</i> : WP2uvrA
Metabolic Activation System	S9 mix from phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	Test 1 a) With metabolic activation: 50 - 5000 µg/plate b) Without metabolic activation: 50 - 5000 µg/plate Test 2 a) With metabolic activation: 230 - 5000 µg/plate b) Without metabolic activation: 230 - 5000 µg/plate
Vehicle	Dimethylsulphoxide
Remarks - Method	The dose selection for the main tests was based on toxicity observed in the range-finding study carried out at 50 - 5000 µg/mL (plate incorporation procedure) and at 500 - 5000 µg/mL (pre incubation procedure).
	Positive controls: With metabolic activation: 2-aminoanthracene (TA1537, TA100, TA1535, WP2uvrA); benzo(a)pyrene (TA98) Without metabolic activation: ICR 191 (TA1537); 4-nitro-o-phenylenediamine (TA98); nitrofurantoin (TA100), sodium azide (TA1535); 4-nitroquinolin-1-oxid (WP2uvrA)

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent				
Test 1	> 5000	> 5000	*	Negative
Test 2		> 5000	*	Negative
Present				
Test 1	> 5000	> 5000	*	Negative
Test 2		> 5000	*	Negative

* It was stated in the study report that the test substance precipitated and the precipitation was concentration-related.

Remarks - Results	<p>No significant increases in the frequency of revertant colonies were noted for any of the bacterial strains, with any concentration of the teste substance, either with or without metabolic activation.</p> <p>The positive and negative controls gave a satisfactory response confirming the validity of the test system.</p>
CONCLUSION	<p>The test substance was not mutagenic to bacteria under the conditions of the test.</p>
TEST FACILITY	<p>Dr U Noack-Laboratorien (2007a)</p>

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Durazane 1500 (> 60 % notified polymer)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	<i>Danio rerio</i>
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	67 mg CaCO ₃ /L
Analytical Monitoring	None
Remarks – Method	No significant deviations from the test guidelines were reported. The test solutions were prepared by direct mixing of the test substance with the test media by an ultraturax at 17,000 rpm in 1 minute. The test vessels were covered and 24 hours after the addition of the test substance the fish were introduced.

RESULTS

Concentration mg/L		Number of Fish	Mortality (%)			
Nominal	Actual		24 h	48 h	72 h	96 h
25	Not determined	7	0	0	0	0
50	Not determined	7	29	29	29	29
100	Not determined	7	100	100	100	100
200	Not determined	7	100	100	100	100
400	Not determined	7	100	100	100	100

LC50 57.1 (95% CI of 55.8-58.4) mg/L at 96 hours (calculated using sigmoidal dose-response regression, using nominal concentrations).

Remarks – Results All validity criteria for the test were satisfied. Oxygen saturation concentration was $\geq 92\%$ during the test at 21-22°C, and mortality in the control was 0%. pH of the control without the notified polymer was between 7.48-7.87 during the test, while an increased in pH (in direct proportion to the addition of the test substance to the water) was observed in the test water, which gradually decreased over time. That increase in pH is possibly due to the addition of the test substance to the water, subsequently rapidly hydrolysing to produce ammonia which could cause toxicity to fish, the ammonia was then gradually evaporated from the test solution resulting in a gradual pH decrease. The toxic effects were observed within 24 hours of initiation of the study.

CONCLUSION The test substance is harmful to fish.

TEST FACILITY Dr U Noack-Laboratorien (2007b)

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