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

PUBLIC REPORT

Bayhydur XP 2547

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 Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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

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**Director
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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 SUBSTANCE	INTRODUCTION VOLUME	USE
STD/1411	Bayer Material Science Pty Ltd	Bayhydur XP 2547	Yes	≤20 tonnes per annum	Component of surface coatings for industrial applications

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided and the presence of the isocyanate functional group in the notified polymer, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008, (2004)] with the following risk phrases:

R37/38 Irritating to respiratory system and skin
 R42/43 May cause sensitisation by inhalation and skin contact

Based on the information on an analogue of the notified polymer, the notified polymer should be considered as though it is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008 (2004)] with the following risk phrase:

R23 Toxic by inhalation

The classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2009) is presented below.

	<i>Hazard category</i>	<i>Hazard statement</i>
Acute inhalation	3	Toxic if inhaled
Specific target organ toxicity, single exposure; Respiratory tract irritation	3	May cause respiratory irritation
Skin irritation	2	Causes skin irritation
Respiratory sensitisation	1	May cause allergy or asthma symptoms or breathing difficulties if inhaled
Repeated exposure	1	Causes damage to organs (respiratory system) through prolonged or repeated inhalation exposure
Skin sensitisation	1	May cause an allergic skin reaction

Human health risk assessment

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

Based on 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

- Based on the data provided for the notified polymer and an analogue, the following risk phrases should be used for products/mixtures containing the notified polymer:
 - Conc \geq 20%: R23, R37/38, R42/43
 - $2\% \leq$ Conc < 20%: R23, R42/43
 - $1\% \leq$ Conc < 3%: R42/43

Health Surveillance

- As the notified polymer is a skin sensitiser and a potential respiratory sensitiser, based on the presence of isocyanate groups, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a history of sensitivity, asthma or other pulmonary condition.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid inhalation of vapours, mists and aerosols
 - Avoid contact with skin and eyes
 - The Safe Work Australia exposure standard for isocyanates of 0.02 mg/m³ (TWA) and 0.07 mg/m³ (STEL) should be observed ([NOHSC:3008 (1995)] and [NOHSC:1003 (1995)])
- Employers should implement the following safe engineering controls to minimise occupational exposure during handling of the notified polymer:
 - Ventilation system, including local exhaust ventilation
 - Ventilated spray booths during spray application, where possible
 - Spray application to occur in well-ventilated areas when spray booths cannot be used
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Safety glasses
 - Coveralls
 - Isocyanate-resistant gloves
 - Appropriate respiratory protection

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

- Spray application should be carried out in accordance with the Safe Work Australia National Guidance Material for Spray Painting [NOHSC (1999)].
- Atmospheric monitoring should be conducted to measure workplace concentrations of isocyanates during reformulation and use of products containing the notified polymer. Employers should ensure that the exposure standard for isocyanates [NOHSC: 1003(1995)] is not exceeded for all areas where the notified polymer will be handled.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]

workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken by the notifier regarding storage of the notified polymer:
 - Check all containers against leakage and ensure lids and caps are tightly sealed.
 - Store in a ventilated and bunded area.
 - Store in a cool dry place away from direct sunlight.
 - Store away from acids, alkalis or amines.

Emergency procedures

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

Regulatory Obligations

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(2) of the Act; if
 - the function or use of the polymer has changed from a hardener in surface coatings for industrial applications, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 20 tonnes per annum, 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.

Material Safety Data Sheet

The MSDS of the notified provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Bayer MaterialScience Pty Ltd (ABN 18 086 237 765)
17-19 Wangara Road, CHELTENHAM VIC 3129

NOTIFICATION CATEGORY

Standard: Synthetic polymer with Mn <1000 Da (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular formula, structural formula, molecular weight, polymer constituents, residual monomers/impurities, analytical data and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: melting point, partition coefficient, adsorption/desorption, dissociation constant, flammability, explosive properties, repeated dose toxicity, biodegradability and bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Bayhydur XP 2547 (>99% notified polymer)

MOLECULAR WEIGHT

Mn >500 Da.

ANALYTICAL DATA

Reference IR, GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at ambient temperature
Boiling Point	1008°C at 101.3 kPa	Estimated using MPBPVP v.143 (US EPA 2008)
	ca. 122°C at 0.1013 kPa	MSDS
Density	1150 kg/m ³ at 20°C	MSDS
Vapour Pressure	ca. 2.2 kPa at 20°C	MSDS
Water Solubility	Not determined	Expected to be water dispersible initially in water due to hydrophilic functionality. However, contains end groups that readily react in water to form carbon dioxide and insoluble high molecular weight polymers.
Hydrolysis as a Function of pH	Rapid	Contains end groups that readily react with water to form carbon dioxide and insoluble high molecular weight polymers. The backbone of the notified polymer contains groups that are expected to hydrolyse very slowly in the environmental pH range (4-9).

Partition Coefficient (n-octanol/water)	Not determined	Expected to react with water and octanol to form carbon dioxide and insoluble high molecular weight polymers
Adsorption/Desorption	Not determined	Not tested due to hydrolytic instability
Dissociation Constant	Not determined	The notified polymer is a salt with the potential to dissociate under environmental conditions
Particle Size	Not determined	Liquid at ambient temperature
Flash Point	ca. 185°C	MSDS
Flammability	Not determined	Not expected to be flammable
Autoignition Temperature	ca. 445°C	MSDS
Explosive Properties	Not determined	Not expected to be explosive based on structure
Oxidising Properties	Not determined	Not expected to be oxidising based on structure

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity

The notified polymer is expected to be stable while stored in sealed vessels with no exposure to the atmosphere. On contact with water the isocyanate groups within the polymer will hydrolyse to an amine which will undergo crosslinking with other isocyanate groups within the polymer.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported neat (> 99% purity) in a liquid form.

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>	<20	<20	<20	<20	<20

PORT OF ENTRY

Melbourne, Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

Bayer Material Science Pty Ltd

TRANSPORTATION AND PACKAGING

The notified polymer will be imported neat (at >99% purity) in 60 kg or 215 kg steel drums. It will be transported from the dock to the notifier's warehouse facility and then distributed to customer sites by road. At the customer's site, the notified polymer will be re-packed into 1 L and 5 L steel cans and distributed to end-users by road.

USE

The notified polymer will be used neat as a hardener in 2-pack coatings for use in industrial settings such as flooring and automotive applications.

OPERATION DESCRIPTION

Repacking

At the customer's site prior to distribution to end-users, the notified polymer will be repacked from the import containers (60 kg or 215 kg) to final containers (1 L or 5 L steel cans) using a metering pump under local exhaust ventilation.

End-use

The neat notified polymer (the hardener) will be mixed manually or in a fit-for-purpose mixing apparatus with the polyol component of the 2-pack coating to form the finished coatings containing the notified polymer at $\leq 75\%$ concentration that will be applied by spray, roller or brush.

Spray Painting

Spray applications will occur in a spray booth where feasible. In other applications spraying directly on to a substrate like concrete may occur *in situ*. When spraying is to be undertaken the mixed coating will be transferred to a reservoir and attached to spray equipment for application. The reservoir may be a pressure pot or a cup attached to the spray gun that feeds the gun through aspiration or gravity.

The worker may take the coating into a spray booth, which could be a downdraft, partial downdraft or a cross-draft type of booth. For automotive applications, the coating will be applied to the car either to a selected small spot, a body panel or the entire car depending on the size of the area under repair.

Roller and Brush Painting

For coating of floors, the mixed coating containing the notified polymer will be poured into a roller tray and applied to the floor manually using a roller or brush and allowed to dry.

Excess coating containing the notified polymer not used will be disposed of into a hazardous waste container, where it will be present in a cross-linked form since the two parts of the coating system have been mixed. Spray, roller or brush equipment will be cleaned with an appropriate solution or solvent. Washings will also be collected into hazardous waste containers.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
<i>Transport and storage</i>	2-4	1-2	20
<i>Repacking</i>	2-4	4-8	20
<i>QC staff</i>	1-2	1	20
<i>Maintenance</i>	1-2	1-2	20
<i>Spray, roller or brush painting</i>	100-1000	8	300

EXPOSURE DETAILS

Transport and storage

Transport and warehousing workers may experience dermal and ocular exposure to the notified polymer through accidental leaks and spillages.

Repacking

Workers may be exposed to the neat notified polymer via the dermal and ocular routes in the event of spills and leaks, during dispensing from imported containers and during connecting filling lines to fill product containers. Workers are expected to wear coveralls, goggles and impervious gloves to minimise dermal and ocular exposure. Aerosols may also be released, but inhalation exposure is likely to be low due to the local exhaust ventilation system and the enclosed system in use. Where ventilation is inadequate a respirator is expected to be worn.

There is potential for dermal exposure during equipment maintenance. However, workers are expected to wear coveralls, goggles and gloves to minimise such exposure.

End-use

Spray painting

Spray painters may come into contact with the notified polymer through dermal and ocular routes from direct contact with drips, spills and splashes during mixing (>99% notified polymer) and transfer of the two-part coating ($\leq 75\%$ notified polymer) to the spraying equipment, manual paint application, and equipment cleaning and maintenance.

Workers may also be exposed to the notified polymer ($\leq 75\%$ concentration) by inhalation of paint aerosols during spray application. In the majority of car repair shops exposure is expected to be minimised by the use of a ventilated spray booth by workers using protective equipment. In car repair shops where spray booths are not used the level of exposure per application is expected to be greater, however, exposure will be minimised by application taking place in a well-ventilated area and the use of personal protective equipment (PPE) such as respirator, gloves, goggles and protective clothing in accordance with the MSDS. Similar measures are expected to be implemented for spraying other substrates, such as concrete *in situ*, except that spraying will occur predominantly in open areas.

After application and once dried, the mixed coating containing the notified polymer is expected to be reacted fully into an inert matrix and the polymer will be unavailable for exposure.

Roller and brush painting

Roller and brush painters may come into contact with the notified polymer through dermal and ocular routes from direct contact with drips, spills and splashes during mixing (>99% notified polymer) and transfer of the mixed coating ($\leq 75\%$ notified polymer) to vessels or trays, manual coating application, and equipment cleaning and maintenance. Exposure would be minimised by the use of gloves, coveralls and goggles.

After application and once dried, the mixed coating containing the notified polymer will react fully into an inert matrix and the polymer will be unavailable for exposure.

6.1.2. Public Exposure

The notified polymer will not be available to the public. The public may come into dermal contact with surfaces and articles coated with coatings containing the notified polymer ($\leq 75\%$ concentration) into an inert matrix in which it will be unavailable for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 > 0.055 mg/L/6 hour
Rabbit, skin irritation	irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

In addition, published data/information on a structurally similar analogue of the notified polymer (1, 6-hexamethylene diisocyanate (HDI); CAS No. 822-06-0) is available and, where relevant, is briefly discussed.

Toxicokinetics, metabolism and distribution

The notified polymer has a molecular weight < 1000 Da and contains a significant proportion of low molecular weight species (i.e. < 500 Da), hence absorption across biological membranes may occur. However, absorption may be limited as the notified polymer in contact with water will form carbon dioxide and insoluble inert polyurea compounds.

Acute toxicity

The notified polymer was tested in a single dose acute oral toxicity study in 2 groups of 3 female rats at 2000 mg/kg bw according to OECD TG 423. No mortalities or signs of systemic toxicity were reported in any of the treated animals (Bayer HealthCare AG, 2006a). Based on the results of this study, the notified polymer is of low acute oral toxicity.

An acute inhalation toxicity study on the notified polymer was conducted according to OECD TG 403 in male rats. Animals were exposed to aerosols of the notified polymer at concentrations of 3.1, 17.9 and 54.5 mg/m³ for 6 hours with effects observed in animals in the 17.9 and 54.5 mg/m³ groups, such as ungroomed hair-coat, piloerection, irregular breathing patterns, tachypnea, laboured breathing patterns, red encrustations on the nostrils, serous nasal discharge, stridor, limp, bradypnea, decreased body weights and hypothermia. Analysis of the bronchoalveolar lavage fluid of animals in the 17.9 and 54.5 mg/m³ groups reported elevated levels of protein, increased total cell counts, increased phospholipids and an initial decrease in total cell counts associated with increased concentrations of N-acetyl- β -D-glucosaminidase (β -NAG). However, most changes declined rapidly up to Day 3 and were resolved by Day 7. The NOAEL was determined to be 3.1 mg/m³ based on the effects observed in the analysis of bronchoalveolar lavage fluid from animals in the mid- and high-dose groups (see Appendix B for details). Given there were no mortalities in this study the LC50 is determined to be > 0.055 mg/L/6 hr. As this value falls within the classifiable range under the Approved Criteria (i.e. LC50 > 5 mg/L/4 hr is not classified as a hazardous substance), further studies using higher doses are required in order to determine the LC50 and classification status of the notified polymer. However, given an analogue of the notified polymer (HDI) is classified as R23 'Toxic by inhalation' (HSIS, 2012), the notified polymer should also be considered similarly classified for acute inhalation toxicity with the same cut-off concentrations as for HDI.

Irritation and Sensitisation

The notified polymer was determined to be irritating to the skin and slightly irritating to the eye of rabbits (see Appendix B for details). Based on the acute inhalation toxicity study described above, the notified polymer is irritating to the respiratory tract.

The notified polymer was found to have the potential for skin sensitisation according to a modified mouse LLNA study including the Integrated Model for the Differentiation of Skin (IMDS) reactions. The stimulation index (SI) for cell counts was reported to exceed 1.4 at concentrations of 10% and 50% and the EC 1.4 value (considered to be the threshold for a sensitisation response in this test protocol) was calculated to be 4.24% (See Appendix B for details).

According to the Approved Criteria (NOHSC 2004), substances containing isocyanate functional groups should be classified as hazardous if there is no evidence to indicate that the substance does not cause respiratory hypersensitivity. Thus, the following risk phrase should be applied to the notified polymer:

R42 May cause sensitisation by inhalation.

Repeated Dose Toxicity

No repeated dose toxicity studies were available on the notified polymer. However, eye irritation and lesions in the nasal cavity have been reported in rats exposed to an analogue of the notified polymer (HDI) in a 21-day inhalation study (NOEL = 0.034 mg/m³) (OECD SIDS, 2001). Based on the structural similarities between the notified polymer and analogue, the effects observed in the repeated dose inhalation toxicity study on the analogue and the demonstrated acute inhalation toxicity for the notified polymer, repeated inhalation exposure to the notified polymer is also expected to lead to adverse effects to the respiratory tract.

Mutagenicity

The notified polymer was not mutagenic under the conditions of an AMES test (see Appendix B for details).

Carcinogenicity

Rats exposed to an analogue of the notified polymer (HDI) via repeated inhalation in a chronic toxicity study were reported to have adverse nasal lesions related to treatment at 0.17 and 1.115 mg/m³ (NOAEL = 0.034 mg/m³). Adverse lesions included non-neoplastic lesions of the nasal cavity. However, HDI was not considered to be a carcinogen (OECD SIDS, 2001). Based on this information, the notified polymer is not expected to be carcinogenic.

Toxicity for reproduction

No adverse reproductive or developmental effects were reported in rats exposed to an analogue of the notified polymer (HDI) via repeated inhalation at concentrations up to 2.1 mg/m³ (OECD SIDS, 2001). Based on this information, the notified polymer is not expected to be toxic to the reproductive system or cause adverse developmental effects.

Health hazard classification

Based on the data provided and the presence of the isocyanate functional group in the notified polymer, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous*

Substances [NOHSC:1008, (2004)] with the following risk phrases:

R37/38 Irritating to respiratory system and skin

R42/43 May cause sensitisation by inhalation and skin contact

Based on the information on an analogue of the notified polymer (HDI), the notified polymer should be considered as though it is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008 (2004)] with the following risk phrase:

R23 Toxic by inhalation

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer will be handled neat by workers involved in repacking as well as application of 2-part coatings. The notified polymer is toxic by inhalation, irritating to the respiratory system and skin, slightly irritating to the eyes, and is considered a respiratory and skin sensitiser.

Inhalation exposure of workers to the notified polymer may occur, particularly inhalation of aerosols of the notified polymer (at up to 75% concentration) during end-use spray application. The majority of spray application is expected to take place in ventilated spray booths with respiratory protection that should lower the potential for inhalation exposure to occur and thus also the potential for adverse respiratory effects. When spray operations do not occur in spray booths there is a greater risk of adverse respiratory effects. This risk should be lowered by ensuring that the application area is well ventilated and that appropriate respiratory protection is worn.

Employers should ensure that airborne levels of isocyanates remain below the exposure standard set by Safe Work Australia in all areas where spray operations occur [NOHSC: 1003(1995)]. Where respiratory protection is deemed to be appropriate for reducing isocyanate exposure, it should consist of an appropriately fitted and maintained air-line respirator or self-contained breathing apparatus complying with the appropriate Australian Standard.

Irritation and sensitisation may occur as a result of dermal exposure to the notified polymer at concentrations >75% during re-packing and ≤75% during end-use. Dermal exposure is expected to be minimised by the wearing of personal protective equipment by workers, including gloves, goggles, and coveralls.

In summary, the risk to workers associated with exposure to the notified polymer is not considered unreasonable provided that the stated engineering controls (particularly spray booths), safe work practices and appropriately fitted and maintained PPE (respiratory protection, gloves, goggles and coveralls) are used.

6.3.2. Public Health

The public will only come into contact with surfaces coated with products containing the notified polymer (≤75% concentration) when it is trapped within a cured polymer matrix and therefore is not expected to be bioavailable for exposure. Therefore, the risk to the public 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 release of the notified polymer to the environment during importation, storage, and transport is expected due to accidental spills. Up to 0.2% of the import volume is expected to be lost during spillage. If a spill occurs during storage or transportation, products containing the notified polymer are expected to be absorbed into inert materials (e.g. sand, soil, vermiculite etc) and collected into suitable containers for disposal to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer in reformulation wastes, container residues and fully cured solid wastes are expected to be collected and sent to landfill. The main release as overspray (35%) during use will typically entail landfill disposal, after interception by spray booth filters. Equipment used to apply the coating formulations may be rinsed with solvent. It is expected that a small amount ($\leq 1\%$) of the notified polymer from cleaning of equipment will be collected, treated and disposed of to landfill in accordance with local, State and Federal regulations. Once cured, the coatings containing the notified polymer will form an inert polymer matrix, and the incorporated notified polymer will not be bioavailable.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in coatings is expected to share the fate of the articles to which it has been applied. The notified polymer in coatings will therefore either be thermally decomposed during metal reclamation processes or disposed of to landfill.

7.1.2. Environmental Fate

A study submitted by the notifier indicates that an analogue of the notified polymer is not readily biodegradable but it does hydrolyse rapidly. The majority of the notified polymer is expected to be cured into an inert matrix as part of its use in coating systems on concrete, timber or metal substrates. The notified polymer is irreversibly bound into the matrix and is not expected to be bioavailable or bioaccumulative. The notified polymer in solid waste disposed of to landfill, is not expected to be mobile and will slowly degrade *in situ*, primarily by biotic and abiotic processes. The notified polymer will eventually degrade in landfill or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon, nitrogen and sulphur.

Significant amounts of the notified polymer are not expected to be released to the aquatic environment. However, if residues are washed to sewer from cleaning of formulation and application equipment, the notified polymer is expected to hydrolyse rapidly and partition to sludge during sewage treatment. Bioaccumulation of the notified polymer is unlikely due to its high molecular weight and its limited release to surface waters. For the details of the environmental fate study please refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

A predicted environmental concentration was not determined because the notified polymer reacts rapidly with water to form carbon dioxide and insoluble inert polyurea compounds. Further, aquatic exposure of the notified polymer is not expected based on the reported use pattern.

7.2. Environmental Effects Assessment

The results from an ecotoxicological investigation conducted on the test substance (hydrolysis products of the notified polymer) are summarised in the table below. Details of these studies can be found in Appendix C.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
<u>Acute Toxicity</u>		
Fish	96 h LL50 = 35.2 mg/L	Harmful to fish
Daphnia	48 h EC50 > 100 mg/L	Not harmful to aquatic invertebrates
Algal	72 h ErC50 = 71.5 mg/L	Harmful to algae

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the test substance is classified as acutely harmful to fish and algae but not harmful to aquatic invertebrates. Note that the notified polymer reacts with water and produces carbon dioxide and hydrolysis products hexamethylene diamine (HDA) and polyurea. Therefore, the ecotoxicity test results reported above are not considered fully reliable as the real concentration of the test substance in water is neither analytically determinable nor it is reproducible. Therefore, the notified polymer is considered not classifiable for its toxicity to test organisms.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as no aquatic exposure is expected based on its reported use pattern.

7.3. Environmental Risk Assessment

The risk quotient ($Q = PEC/PNEC$) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its assessed use pattern.

The majority of the notified polymer will ultimately be disposed of to landfill as cured polymer. In its cured state, the notified polymer is irreversibly bound within an inert matrix, and is not expected to be bioavailable or mobile. If the notified polymer is released to surface waters, it is expected to hydrolyse on contact with water to form intractable polymeric masses which are expected to be neither bioavailable nor bioaccumulative. Based on its limited environmental exposure, notified polymer is not considered to pose an unreasonable risk.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Hydrolysis as a Function of pH**

Rapid

Method	OECD TG 111 Hydrolysis as a Function of pH.
Remarks	The test substance was stirred in demineralised water for 18 hours at ambient temperature rather than 50°C since the hydrolysis was expected to proceed rapidly. As isocyanates are known to be highly reactive in all aqueous media only a negligible influence of pH is expected and therefore all tests were performed in water and no pH value was determined. The test substance hydrolysed immediately. A sample was filtered and analysed by high performance liquid chromatography with mass spectrometry detection. There was no signal corresponding to the test substance. Another sample was dried under vacuum and analysed by infra-red spectroscopy. There was no signal corresponding to the reactive end group.
Test Facility	Bayer Industry Services GmbH & Co. OHG (2006a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – inhalation

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 403 Acute Inhalation Toxicity. EC Council Regulation No 440/2008, 92/69/EEC B.2 Acute Toxicity (Inhalation).
Species/Strain	Rat, Hsd Cpb: WU (SPF)
Vehicle	None
Method of Exposure	Nose-only
Exposure Period	6 hours
Physical Form	liquid aerosol
Particle Size	~2 µm
Remarks - Method	The study was conducted with minor variations to the OECD test guidelines. However, there were no significant protocol deviations.

Bronchoalveolar lavage fluid (BALF) was analysed for protein as an index of air-blood barrier permeability; phosphatidylcholine in BALF served as an indicator of alterations in surfactant homeostasis. Lactate dehydrogenase (LDH) was measured as an indicator of cell injury. N-acetyl-β-D-glucosaminidase (β-NAG) was measured as an indicator of lysosomal instability. These endpoints were determined on the exposure day and on post exposure days 1, 3 and 7.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Concentration mg/m³</i>		<i>Mortality</i>
		<i>Nominal</i>	<i>Actual</i>	
1	6 M	0	0	0/6
2	6 M	3.0	3.1	0/6
3	6 M	15.0	17.9	0/6
4	6 M	50.0	54.5	0/6

LC50
Signs of Toxicity

> 0.055 mg/L/6 hours (NOAEL = 3.1 mg/m³)
There was a statistically significant decrease in body weight from days 1-3 of the study period in the 54.5 mg/m³ group compared to controls. The decrease was not observed on day 7 of the study.

A statistically significant decrease in rectal temperatures was reported in the 17.9 mg/m³ (36.7°C) and 54.5 mg/m³ (35.6 °C) groups.

Piloerection, labored breathing patterns, red encrustations on the nostrils, serous nasal discharge, stridor, limp and bradypnea were observed in animals in the 54.5 mg/m³ group. In addition, ungroomed hair-coat, irregular breathing patterns and tachypnea were observed in animals in the 17.9 mg/m³ and 54.5 mg/m³ groups.

Samples of bronchoalveolar lavage fluid (BALF) were taken from test animals on Days 0 (3 hours after exposure), 1, 3 and 7 to investigate indicators of an inflammatory response, lower respiratory tract damage and interactions with pulmonary phospholipids. Statistically significant differences to the control group for these parameters are presented in the table below. The results showed increased levels for all parameters in the mid- and high exposure groups that was maximal on the exposure day and Day 1. All the effects rapidly declined and were resolved by Day 7.

<i>Parameter</i>	<i>Dose (mg/m³)</i>			
	0	3.1	17.9	54.5
Lactate dehydrogenase			++ (Day 0, 1)	++ (Day 0, 1)
Protein			++ (Day 0,1)	++ (Day 0, 3) + (Day 1)
Phospholipids			++ (Day 0, 1)	+ (Day 1) ++ (Day 3)
β-NAG			++ (Day 0)	++ (Day 0)

+ Statistically significant increase (p<0.05)

++ Statistically significant increase (p<0.01)

Effects in Organs

Absolute lung weights were significantly increased in animals in the 17.9 mg/m³ group on Day 0 and relative lung weights in this group were significantly increased on Days 0, 1 and 3, resolving by Day 7.

Absolute and relative lung weights were significantly increased in animals in the 54.5 mg/m³ group on Days 0, 1 and 3, resolving by Day 7.

Macroscopic examination of the lungs showed discolouration (red, brown, grey and white) in all test animals including controls with an increased incidence in the 54.5 mg/m³ group. One animal in the 17.9 mg/m³ group and 2 animals in the 54.5 mg/m³ group showed enlarged lung-associated lymph nodes.

Remarks - Results

The increased concentration of lactate dehydrogenase (LDH) in the 17.9 and 54.5 mg/m³ groups on Days 0 and 1 indicate cytotoxicity in lung cells.

The increased concentration of protein in the 17.9 and 54.5 mg/m³ groups indicate decreased permeability of the air-blood barrier in the lungs. The increased lung weight observed in these groups may also be an indication of damage to the air-blood barrier.

The increased concentration of phospholipids in BALF in the 17.9 and 54.5 mg/m³ groups indicate that surfactant homeostasis of the epithelial lining of the lungs has been altered.

The increased concentration of β-NAG in the 17.9 and 54.5 mg/m³ groups on the day of dosing indicate an immediate inflammatory response to exposure to the notified polymer.

The changes observed in the BALF analysis indicate that the notified polymer is irritating to the respiratory tract.

Most changes declined rapidly up to Day 3 and were resolved by Day 7.

CONCLUSION

The notified polymer is determined to have a LC₅₀ > 0.055 mg/L/6 hours.

TEST FACILITY

Bayer AG (2003)

B.2. Irritation – skin

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation).

Species/Strain	EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Number of Animals	Rabbit (Esd:NZW)
Vehicle	3
Observation Period	None
Type of Dressing	14 days
Remarks - Method	Semi-occlusive.
	No significant protocol deviations.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	-	1	2.67	3	>14 days	1
<i>Oedema</i>	-	0.67	1.67	2	>14 days	1

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

-Scoring of irritation was not possible in Animal No. 1 because the patch adhered to the skin.

Remarks - Results	<p>The notified polymer caused the semi-occlusive patch to adhere to the skin. The patch was unable to be removed from Animal No. 1 until Day 7. The patch applied to Animal No. 2 was removed by 24 hrs and the patch applied to Animal No. 3 was removed gradually with scraps still intact at 24-72 hrs which were able to be removed completely on Day 7.</p> <p>Moderate to severe erythema and slight oedema was observed in one animal, reducing to well defined erythema and very slight oedema after 72 hrs. Very slight erythema and oedema was still present in this animal on Day 14. In another animal, very slight erythema was observed, clearing on Day 14. In addition, very slight oedema was observed until 72 hrs following treatment. Removal of the patch applied to the third animal was not possible until Day 7. Immediately following removal, moderate to severe erythema and very slight oedema was observed.</p>
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CONCLUSION The notified polymer is irritating to the skin.

TEST FACILITY Bayer HealthCare AG (2005a)

B.3. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation). EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit (Crl:KBL(NZW)BR)
Number of Animals	3
Observation Period	21 Days
Remarks - Method	No significant protocol deviations.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	2	1	1	2	< 14 days	0
<i>Conjunctiva: chemosis</i>	0.67	0.33	0.33	1	< 72 hrs	0
<i>Conjunctiva: discharge</i>	0	0	0	0	-	0
<i>Corneal opacity</i>	0	0	0	0	-	0
<i>Iridial inflammation</i>	0	0	0	0	-	0

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

Remarks - Results	Conjunctival redness was observed at all observation points up to 72 hrs in 2 animals and up to Day 7 in 1 animal with recovery observed at Day 14. Chemosis was observed in all animals with recovery by 48 hrs for 2 animals and recovery by 72 hrs for 1 animal.
CONCLUSION	The notified polymer is slightly irritating to the eye.
TEST FACILITY	Bayer HealthCare AG (2005b)

B.4. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
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 and Pre-incubation procedure <i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100, TA102 S9 fraction from rat liver induced with Aroclor 1254 Test 1 – Plate incorporation procedure a) With metabolic activation: 50, 158, 500, 1581, 5000 µg/plate b) Without metabolic activation: 50, 158, 500, 1581, 5000 µg/plate Test 2 – Pre-incubation procedure a) With metabolic activation: 14, 25, 140, 250, 1400, 2500 µg/plate b) Without metabolic activation: 14, 25, 140, 250, 1400, 2500 µg/plate
Species/Strain	
Metabolic Activation System	
Concentration Range in Main Test	
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	The plate incorporation and pre-incubation procedures were used in the study.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	-	≥158	-	Negative
Test 2	-	≥140	-	Negative
<i>Present</i>				
Test 1	-	≥158	-	Negative
Test 2	-	≥250	-	Negative

Remarks - Results	Reduced growth of the background lawn was observed in various strains in the absence and presence of the S9 mix as low as 140 µg/plate. However, this was not deemed to interfere with the validity of the tests as the positive controls displayed clear mutagenic effects even at low concentrations.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Bayer HealthCare AG (2005c)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified polymer
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METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain	Mouse/Hsd Win:NMRI
Vehicle	Acetone/Olive oil (4:1)
Remarks - Method	The LLNA was modified to include the Integrated Model for the Differentiation of Skin (IMDS) reactions. Instead of using radioactive labelling, lymph node cell counts and weights were measured to indicate sensitising potential. Ear thickness and ear weight measurements were used to indicate irritant potential. This modification meets the performance standards prescribed in Annex I to OECD TG 429. Raw data such as the weights of the draining lymph nodes, the width of the lymph nodes and the cell counts for the lymph nodes were not included in the study report. Data on positive controls was not included in the study report.

RESULTS

<i>Concentration (% w/w)</i>	<i>Proliferative response (Relative cell Count)</i>	<i>Lymph node weight (Test/Control Ratio)</i>	<i>Ear swelling (Test/Control Ratio)</i>	<i>Ear weight (Test/Control Ratio)</i>
<i>Test Substance</i>				
0 (vehicle control)	1.00	1.00	1.00	1.00
2	1.07	0.92	1.03	0.96
10	2.25	1.78	1.23	1.13
50	1.95	1.63	1.51	1.41

Remarks - Results	<p>A positive sensitisation response is indicated by a relative cell count exceeding 1.4 based on previous studies in this test system at this facility. Therefore, the relative cell counts for the groups treated with 10% and 50% notified polymer (2.25 and 1.95) indicate that it was sensitising at these concentrations.</p> <p>The threshold for a positive irritation response is ear swelling of at least 2×10^{-2} mm. The raw data on ear swelling measurements was not included in the study report but the study authors claim that an irritation response was observed for the groups treated with the notified polymer at 10% and 50%.</p> <p>A differentiation index was used to calculate the contribution of irritation to the inflammation observed. The irritation response is quantified by the quotient of the relative lymph node reaction divided by the relative acute skin reaction. The study authors calculated a value of 5.45 for the group treated with 10% which indicates sensitisation. The study authors calculated a value of 0.96 for the group treated with 50% which indicates an overall irritating potential. The study report did not include the formula or rationale for these calculations and therefore, these values were unable to be verified.</p>
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CONCLUSION	There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.
TEST FACILITY	Bayer HealthCare AG (2006b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue of notified polymer
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I). OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sludge from ten locations comprising samples from effluent of municipal sewage treatment plants including surface water and extract of surface soil from river, lake and sea.
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	BOD, cationic component by LC-MS, anionic components by HPLC, TOC, water soluble products by LC-MS.
Remarks - Method	According to the OECD guidelines above, a ready biodegradability test was carried out using the test substance (100 mg/L), activated sludge (30 mg/L) incubated under darkness for 28 days at $25 \pm 1^\circ\text{C}$.

RESULTS

<i>Test substance</i>		<i>Aniline</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
7	0	7	71
14	-1	14	76
21	-1	21	77
28	-1	28	77

Remarks - Results	The test substance was completely dissociated into the cationic and anionic components under the test conditions. The cationic component was not biodegraded by microorganisms. Most of the anionic component was polymerized into products insoluble in various solvents. The rest of the anionic component was converted into water soluble products. The converted products were not biodegraded by microorganisms. All validity criteria for the test were satisfied. The reference substance, aniline was degraded >60% by the 10 th day, indicating a suitable aerobic activated sludge inoculum was used. The test substance did not reach the pass level of 60% degradation for this test and therefore cannot be classified as readily biodegradable.
CONCLUSION	The test substance, and by inference the notified polymer, is not readily biodegradable.
TEST FACILITY	Kurume Laboratory (2006)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static conditions. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – static conditions.
Species	<i>Brachydanio rerio</i>
Exposure Period	96 h
Auxiliary Solvent	None.
Water Hardness	255 mg CaCO ₃ /L
Analytical Monitoring	DOC, oxygen concentration, pH
Remarks – Method	The diluted test substance was stirred for 24 h and the undissolved particles were removed by filtration. The test was conducted at nominal concentrations of 0, 6.3, 12.5, 25, 50, 100 mg/L under static conditions for a period of 96 h according to the guidelines above. The controls were kept in dilution water. Ten fish per test solution were observed for mortality after every 24 hours. Test conditions were: 20 - 24 ± 1°C, pH 7.6-8.0, 5 mg O ₂ /L, 8 hours dark and 16 hours light period.

RESULTS

Concentration mg/L		Number of Fish	Mortality				
Nominal	Actual		2 h	24 h	48 h	72 h	96 h
0		10	0	0	0	0	0
6.3		10	0	0	0	0	0
12.5		10	0	0	0	0	0
25		10	0	0	1	0	0
50		10	0	9	0	0	0
100		10	0	10			
LL50		37.5 mg/L at 24 hours. 35.2 mg/L at 48 hours. 35.2 mg/L at 72 hours. 35.2 mg/L at 96 hours.					
NOELR		12.5 mg/L at 96 hours.					
Remarks – Results		Considering the heterogeneous composition of the test substance in water as the test medium, Water Accommodated Fractions (= WAF's) were tested. The results of the DOC determinations reflect a rough impression only of exposure conditions over time. No information is available on a potential correlation between lethal loadings and measured DOC values. The results are expressed in lethal loadings (LL). Test results are treated with caution as the filtration of the WAF was used instead of siphoning media (after solid had settled) and the test substance reacts with water and produces carbon dioxide and insoluble high molecular weight polymers. Validity criteria were satisfied with no significant deviation from the above guidelines.					

CONCLUSION The test substance is potentially harmful to fish.

TEST FACILITY Bayer Industry Services GmbH & Co OHG (2006b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – static conditions. Acute Immobilisation Test.

Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None.
Water Hardness	271.32 mg CaCO ₃ /L
Analytical Monitoring	DOC, pH and dissolved oxygen
Remarks - Method	The diluted test substance was stirred for 24 h and the undissolved particles were removed by filtration. After a range finding test, a definitive test at concentrations 0, 25, 50 and 100 mg notified polymer/L was conducted according to the guidelines above. Two replicates per concentration each had 10 daphnia added. The daphnia were observed for immobilisation every 24 hours over the course of the test. Test conditions were: 18 -22°C, 16 h/8 h light dark cycle, 7.9 – 8.2 mg O ₂ /L, pH 7.9-8.6.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h [acute]	48 h [acute]
0		20	0	0
25		20	0	0
50		20	0	3
100		20	1	5

EL50 >100 mg/L at 48 hours [acute]

NOELR 25 mg/L at 48 hours [acute]

Remarks - Results The results are expressed in effective loadings (EL). Considering the heterogeneous composition of the test substance in water as the test medium, Water Accommodated Fractions (= WAF's) were tested. The results of the DOC determinations reflect a rough impression only of exposure conditions over time. No information is available on a potential correlation between effective loadings and measured DOC values. Test results are therefore, used with caution as the filtration of the WAF was used instead of siphoning media (after solid had settled) and the test substance reacts with water and produces carbon dioxide and insoluble high molecular weight polymers. Validity criteria for the test were satisfied with no significant deviation from the guidelines.

CONCLUSION The test substance is not harmful to aquatic invertebrates.

TEST FACILITY Bayer Industry Services GmbH & Co OHG (2006c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Acute Toxicity for Fish – static conditions Council Regulation No 440/2008 C.3 Algal Inhibition Test.
Species	<i>Desmodesmus subspicatus</i>
Exposure Period	72 hours
Concentration Range	Nominal: 0 – 100 mg/L
Auxiliary Solvent	None
Water Hardness	Not provided
Analytical Monitoring	pH, DOC, Cell counts were performed using a microcell counter and microscopic counting chamber.
Remarks - Method	After a range finding test, a definitive test was conducted to assess adverse effects on algae according to the above guidelines. Algal cells

were exposed for a period of 72 h to a range of concentrations, nominally 6.3, 12.5, 25, 50 and 100 mg/L of the notified polymer. Test conditions were: 21-25°C, continuous uniform illumination, pH 8.0-8.9. Probit analysis and dunnett's comparison were used for statistical analysis.

RESULTS

<i>Biomass</i>		<i>Growth</i>	
<i>EbL50</i> mg/L at 72 h	<i>EbL10</i> mg/L at 72	<i>ErL50</i> mg/L at 72	<i>ErL50</i> mg/L at 72
42.01	17.86	71.53	20.16

NOELR 12.5 mg/L at 72 h.

Remarks - Results The results are expressed in terms of effective loadings (EL). Considering the heterogeneous composition of the test substance in water as the test medium, Water Accommodated Fractions (= WAF's) were tested. The determination of DOC gives an indication of actual concentration. No information is available on a potential correlation between effective loadings and measured DOC values. Test results are used with caution as the filtration of the WAF was used instead of siphoning media (after solid had settled) and the test substance reacts with water and produces carbon dioxide and insoluble high molecular weight polymers. Validity criteria were satisfied with no significant deviation from the test guidelines.

CONCLUSION The test substance is harmful to algae.

TEST FACILITY Bayer Industry Services GmbH & Co OHG (2006d)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified polymer

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum Activated Sludge (400 mg/L)
Exposure Period 3 hours
Concentration Range Nominal: 0 - 10000 mg/L
Remarks – Method The activated sewage sludge was exposed to the test substance at different concentrations (0, 1000, 1800, 3200, 5600 and 10000 mg/L) for 3 hrs. Test conditions were: 20 ± 2 °C, pH 7.2-7.8 and permanent aeration.

RESULTS
IC50 >10000 mg/L
Remarks – Results All validity criteria for the guideline were satisfied and no significant deviations from the guidelines were reported. About 40% inhibition was seen at 10000 mg/L. Test concentrations were given as nominal concentration and were not confirmed by analytical methods.

CONCLUSION The test substance does not inhibit respiration of waste water microorganisms.

TEST FACILITY Bayer Industry Services GmbH & Co OHG (2005)

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