File No: LTD/1944

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

HANSA® SQ 2050

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.

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

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Director
NICNAS

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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
LTD/1944	CHT Australia Pty Ltd	HANSA® SQ 2050	ND*	≤ 150 tonnes per annum	Component of a soil conditioning agent, fabric softener and two-part polyurethane adhesive system

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited information, 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 environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute category 2	H401 – Toxic to aquatic life
Chronic category 2	H411 – Toxic to aquatic life with long lasting effects

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 its use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment at the maximum use concentration in soil.

Recommendations

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:
  - Enclosed and automated processes, where possible
  - Adequate general ventilation and local exhaust 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:
  - Avoid contact with skin and eyes

- 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:
  - Eye protection
  - Gloves
  - Coveralls
  - Safety boots

- Boom spray applications should be carried out in accordance with the Australian Pesticides and Veterinary Medicines Authority's Spray Drift management guideline or relevant State or Territory Code of Practice.

- 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
  - the polymer has a number-average molecular weight of less than 1,000 Da;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from component of a soil conditioning agent, fabric softener and two-part polyurethane adhesive system, 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 SDS of the notified polymer provided by the notifier was 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)
CHT Australia Pty Ltd (ABN: 54 006 849 869)
33 Elliot Road
DANDENONG SOUTH VIC 3175

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, use details 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/boiling point, specific gravity/density, vapour pressure, hydrolysis as a function of pH, partition co-efficient, absorption/desorption, dissociation constant, flash point, flammability limits, autoignition temperature, explosive properties, oxidising properties and reactivity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada, China and the USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
HANSA® SQ 2050

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference NMR, IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90 %

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: light yellow liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Expected to be < 0 °C
Boiling Point	Not determined	Expected to be > 100 °C. Decomposition is expected to occur prior to boiling point being reached.
Vapour Pressure	Not determined	Expected to have a low vapour pressure

		based on high molecular weight.
Water Solubility	< 0.005 g/L	Measured
Hydrolysis as a Function of pH	Not determined	Significant hydrolysis at environmental pH is not expected given the notified polymer is insoluble in water.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to be surface active based on its structure. Therefore, the notified polymer is expected to partition to phase boundaries.
Adsorption/Desorption	Not determined	Expected to partition to soil surface based on its surface activity.
Flash Point	> 100 °C (pressure unknown)	SDS
Autoignition Temperature	Not determined	Not expected to undergo autoignition.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties.

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 under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

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 either be imported in neat form or as a component of end-use products at ≤ 30% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10–150	10–150	10–50	10–150	10–150

PORT OF ENTRY
Major ports in Australia

IDENTITY OF RECIPIENT
CHT Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 1,000 L intermediate bulk containers (IBC) which will be distributed to end-users.

The notified polymer will be imported and reformulated into end-use products, in 20 or 205 L drums, containing the notified polymer ≤ 30% concentration.

The notified polymer and the reformulated products containing the notified polymer will be transported primarily by road to retail stores in packages suitable for retail sale.

USES
The notified polymer will be used as a:
- soil conditioning agent at 1–5% concentration (> 95% of the total import volume)
- dry-cleaning fabric softener at ≤ 30% concentration (< 5% import volume)

- catalyst in a two-part polyurethane adhesive system at 0.2% concentration (< 5% import volume)

OPERATION DESCRIPTION

The notified polymer will be sent to end-use sites in the original containers or repackaged into 20 or 205 L drums. Where the notified polymer is reformulated (≤ 30% concentration), it will be pumped from the 1,000 L IBC into a blending tank along with solvents and other additives, including emulsifiers. The blended mixture is then pumped to a filling machine and filled into 20 or 205 L drums.

The notified polymer may also be imported in a diluted form (≤ 30% concentration) and repackaged in Australia.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and warehouse	2–6	12–24
Reformulation workers	2–4	12–24
Farmers	100–200	1–5
Dry-cleaning workers	100–200	200
Polyurethane adhesive plant operators	10–20	24–48
Manufacturing workers using adhesives	100–200	200

EXPOSURE DETAILS

Transport and warehouse workers

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

Reformulation

Reformulation of the notified polymer into end-use products will be largely automated. However, reformulation workers may be exposed (via the dermal and ocular routes) to the neat notified polymer when connecting pumping equipment to containers, during transfer of the contents to the blending tank, and during quality control testing. The reformulation workers may also be exposed to the notified polymer at ≤ 30% concentration during filling processes. The reformulation and filling process will take place in a bunded area which is equipped with local ventilation.

Dermal and ocular exposure of the notified polymer to workers should be mitigated through the use of personal protective equipment (PPE) including coveralls, safety boots, impervious gloves and safety glasses.

Farm workers

Dermal and ocular exposure to the notified polymer at 1–5% concentration to farm workers is possible during transferring containers containing the notified polymer from storage sheds into the loading area, opening containers, and connecting pumping equipment to the onsite fertigation water system. Dermal and ocular exposure to workers should be mitigated by the use of personal protective equipment (PPE) including coveralls, safety boots, impervious gloves and safety glasses.

Farm workers may be exposed (dermal and ocular exposure) to the notified polymer when mixing, connecting and disconnecting equipment, and spraying the notified polymer using a boom-sprayer. Workers may also be exposed to the notified polymer at ≤ 5% concentration if the come into contact with fertigation water. Dermal and ocular exposure to workers should be mitigated through the use of personal protective equipment (PPE) including coveralls, gum boots, impervious gloves and safety glasses.

Dry cleaning workers

Dermal and ocular exposure to the notified polymer at ≤ 30% concentration may occur during connecting and disconnecting drums to the fabric softener dosing system (at 10 mL/wash). The potential for exposure will be

minimised via the use of PPE, including impervious gloves, coveralls, safety boots and safety glasses while changing the drums containing the fabric softener. The area where the dry cleaning equipment is located will be equipped with local exhaust ventilation removing aerosols or mists generated near equipment.

Once the cleaning cycle has been completed the notified polymer would be mostly adsorbed onto the cloth fibres and any residual unbound polymer would be removed by the solvent system. No significant exposure to the notified polymer is expected while handling fabrics.

Polyurethane adhesive system
The polyurethane adhesive manufacturing system will be enclosed and largely automated. Workers may be exposed (dermal, and to a lesser extent ocular) to the notified polymer at 0.2% concentration during connecting and disconnecting pumping equipment while transferring the notified polymer to the holding tanks. Exposure to the notified polymer should be mitigated through use of personal protective equipment (PPE) including coveralls, safety boots, impervious gloves and safety glasses.

The notified polymer will be used at low concentrations (0.2%) and once the adhesive is cured the notified polymer will be trapped within the solid matrix of the adhesive.

6.1.2. Public Exposure
The notified polymer will be used in farms and industrial settings and will not be available to the public.

Bystander exposure to the notified polymer during application of the notified polymer via the boom spray is possible, but is expected to be limited based on the proposed use pattern and targets (ground application). Potential routes of exposure for bystanders are dermal and ocular during or immediately after a spraying event, while dermal exposure is the most likely route of exposure during re-entry situations. Adherence to good agricultural practice will minimise potential risks.

Due to the notified polymer's high molecular weight and positive charge, when used in soil treatment it is expected to be absorbed to soil which is then washed from crops during cleaning and processing. Therefore, dietary exposure to the notified polymer is not expected.

When used in dry cleaning, the notified polymer will be adsorbed to the fabric fibres and any unbound polymer will be removed from fabric by the solvent wash cycles of the dry cleaning equipment. The most likely route of exposure will be dermal.

When used in polyurethane adhesive systems the notified polymer will be bound within the cured adhesive matrix and 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 following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 5,000mg/kg bw; low toxicity

Toxicokinetics, metabolism and distribution
Based on the high molecular weight of the notified polymer (> 1,000 Da), the potential for the polymer to be absorbed through skin contact is expected to be limited. However, the notified polymer contains a small portion (< 10%) of low molecular weight species (< 500 Da) that may be able to cross biological membranes.

Acute toxicity
The notified polymer is considered to be of low acute toxicity via the oral route based on a test conducted in rats. No acute inhalation or dermal toxicity data were provided for the notified polymer.

Irritation and sensitisation
The notified polymer contains functional groups that are considered to be a structural alert for skin irritation/corrosion and sensitisation (Barrett et al., 1994; Hulzebos et al., 2005). However, given the high molecular weight of the notified polymer and low percentage (< 10%) of low molecular weight species < 1,000

Da, the potential for irritation and sensitisation is not expected. However, at high concentrations, the potential for the notified polymer to cause adverse skin effects cannot be ruled out.

Health hazard classification
Based on the limited information available, 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.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the available information, the notified polymer may have the potential to cause adverse skin effects at high concentrations.

Irritation or sensitisation potential for reformulation workers is likely during the transfer of the imported neat notified polymer in to the mixing vessels. The expected use of PPE by these workers should reduce exposure levels and lower the likelihood of potential adverse effects.

Although farm workers may be exposed to the notified polymer when handling the soil conditioning agent containing the notified polymer, exposure will be low given the low concentration of the notified polymer (≤ 5%) in the soil conditioning agent and expected use of PPE by farm workers.

Dry cleaning workers may have ocular and dermal exposure to product containing the notified polymer at ≤ 30% during connecting and disconnecting dosing equipment. The exposure is expected to be limited by local exhaust ventilation if any aerosols or mists are generated, and through the use of PPE, including impervious gloves, coveralls, safety boots and safety glasses.

Workers may come into contact with adhesive containing the notified polymer at 0.2% concentration. However, significant exposure of workers to the notified polymer is not expected based on the control measures proposed by the notifier. At the low use concentration, skin effects are not expected from the notified polymer.

Therefore, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
As the notified polymer is only intended to be applied in industrial, agricultural and commercial settings, the direct exposure of members of the public to the polymer is expected to be limited. Given the low volume of the notified polymer used in dry cleaning and expected low hazard, the risk to the public from use of the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported into Australia either in neat form or as a component of end-use products. The notified polymer will be reformulated into end-use products in Australia. The reformulation process will involve blending operations and will take place in a bunded area equipped with local ventilation. Potential release to the environment during reformulation may result from residues in import containers, spills, leaks and solvents for instrument cleaning. All these wastes produced during reformulation are expected to be contained and be disposed of by a licensed waste contractor.

RELEASE OF CHEMICAL FROM USE
Environmental release of the notified polymer during use as soil conditioning agent
Products containing the notified polymer will be pumped into the on-site fertigation water system by farm workers to treat sodic soils. Fertigation water containing the notified polymer will be applied to treated soil by boom spraying or crop irrigation systems. All notified polymer used for soil treatment is expected to be directly released to agricultural soil, with an expected soil concentration of about 250 ppm. Therefore, > 142.5 tonnes of

the notified polymer (> 95% of total import volume used for soil treatment × 150 tonnes/year) will be released to soils.

Environmental release of the notified polymer during use in dry cleaning
The majority of the notified polymer added into dry cleaning equipment will bind to cloth fibres. Any unbound polymer will be removed by solvent used in dry cleaning and be disposed of by a licensed waste contractor. Therefore, no significant release of the notified polymer to the environment is expected from this use pattern.

Environmental release of the notified polymer from use in polyurethane adhesive system
The polyurethane adhesive manufacturing system will be enclosed and largely automated. Once the adhesive is cured the notified polymer will be trapped within the solid matrix of the adhesive. Therefore, no significant release of the notified polymer to the environment is expected from this use pattern.

RELEASE OF CHEMICAL FROM DISPOSAL
A small proportion of the notified polymer may remain in end-use containers following use. Wastes and residues of the notified polymer in empty containers are likely either to share the fate of the container and be disposed of to landfill, or to be removed in solvent for reuse or be safely disposed of by a licensed waste contractor.

7.1.2. Environmental Fate
The notified polymer is not inherently biodegradable (32% biodegradation in 29 days). For the details of the environmental fate studies refer to Appendix C.

Following its use as soil conditioning agent, the majority of the notified polymer is expected to be released directly to agricultural soil. Based on its positive charge and potential surface activity, the notified polymer is expected to sorb to negatively charged soil surface. The notified polymer is not expected to bioaccumulate due to its high molecular weight, and potential surface activity. The notified polymer in soil is expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon, silicon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)
Based on the above release estimation, it can be assumed for the purpose of the risk assessment, that all of the import volume of the notified polymer will be directly released to soils from the use as soil conditioning agent. As indicated in the application dossier, the soil will be treated to achieve concentration of approximately 250 ppm (equal to 250 mg/L) for the notified polymer within the top 30 cm of soil. Assuming a soil density of 1,500 kg/m^3 (EPHC, 2009), the worst case PEC_{soil} of the notified polymer in the top 30 cm of treated soil is approximately 167 mg/kg (= 250 mg/L ÷ 1500 kg/m^3). This calculated PEC_{soil} value is far below the toxicity endpoint of 14 days LC50 > 8,000 mg/kg to a terrestrial organism (*Eisenia Andrei* BOUCHÉ), study summarised in appendix C.

In the majority of Australian topsoils the organic carbon content is 5% or greater, namely 50 g carbon/kg soil or greater (ANRA, 2001) while the organic carbon content in soil contributed by using the notified polymer is expected to be less than 167 mg carbon/kg soil. Therefore, the application of the notified polymer at the recommended rate will not significantly increase the background soil organic carbon levels in carbon-poor soils. Additionally, run-off of the notified polymer from the soil is not expected to be significant as the notified polymer is insoluble in water and not expected to be mobile in soil.

7.2. Environmental Effects Assessment
The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Results (mg/L)*	*Assessment Conclusion*
Fish Toxicity	96 hours LC50 = 24	Harmful to fish
Daphnia Toxicity	48 hours EC50 = 12	Harmful to aquatic invertebrates
Algal Toxicity	72 hours EC50 > 5	May be toxic to algae
Inhibition of Bacterial Respiration	5 minutes EC50 > 1,000	May not be inhibitory to bacterial activity
Earthworm (*Eisenia Andrei* BOUCHÉ)	14 days LC50 > 8,000	Very slightly toxic to earthworm

Based on the above ecotoxicological endpoints for the notified polymer, it is expected to be toxic to algae. Therefore, under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United

Nations, 2009), the notified polymer is formally classified as 'Acute Category 2; Toxic to aquatic life'. Based on the acute toxicity and lack of ready biodegradability of the notified polymer, it is formally classified as 'Chronic Category 2; Toxic to aquatic life with long lasting effects' under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) to aquatic life is not calculated for the notified polymer as the notified polymer is not expected to be significantly released to aquatic systems.

7.3. Environmental Risk Assessment

The notified polymer is a cationic polymer that is expected to predominately exposure to soil from its use as soil treatment. The notified polymer may be toxic to aquatic life but it is not expected to enter to the water system significantly. The calculated PEC_{soil} is far less than the measured toxicity endpoint for terrestrial organism, indicating that the release of the notified polymer from this use pattern is not expected to reach ecotoxicologically significant concentrations in soil. Therefore, on the basis of its use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment at the maximum use concentration in soil.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility < 0.005 g/L

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. Only a study summary is provided and reliability of the result is undetermined.
Test Facility	In-house test

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague Dawley
Vehicle	None
Remarks - Method	GLP Certificate. The test substance was administered by oral gavage.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	6 F	0	0/6
2	6 F	5,000	0/6

LD50	> 5,000 mg/kg bw
Signs of Toxicity	No clinical signs related to the administration of the test substance were recorded.
Effects in Organs	The macroscopical examination of animals at the end of study did not show treatment-related changes.
Remarks - Results	The body weight evolution of the animals remained normal throughout the study, similar between treated and controlled animals.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Phycher Bio-Developpment (2005)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Inherent biodegradability

TEST SUBSTANCE	Product containing notified polymer + 25% butyldiglycol
METHOD	OECD TG 302B CO_2 evolution
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	DOC measurement
Remarks – Method	Only a study summary is provided. It is unclear whether there is significant deviation from the test guideline.

RESULTS

Test substance		*Reference Substance*	
Day	*% Degradation*	*Day*	*% Degradation*
7	26		
14	30	No reference was run during the test	
21	29		
28	29		
29	32		

Remarks – Results	The validity for the test results is unable to be determined. Determination of the biodegradation for a reference compound was not run in parallel. The test results are not reliable to make a conclusion. It can be only used as weight of evidence.
CONCLUSION	The test substance may not be inherently biodegradable.
TEST FACILITY	In-house test

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Product containing the notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	Golden Orfe (*Leuciscus idus melanotus L.)*
Exposure Period	96 hours
Auxiliary Solvent	Butyldiglycol
Water Hardness	Not reported
Analytical Monitoring	Not applicable
Remarks – Method	The test substance is insoluble in water and butyldiglycol was used as solubiliser. The notified substance was mixed with butyldiglycol and stirred for homogenisation. Water was added to this mixture to make a stock solution.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control	-	7	0	0	0	0
10	Not determined	7	0	0	0	0
25		7	2	2	2	3
40		7	2	6	6	6

50	7	7	-	-	-

LC50 24 mg/L at 96 hours.

Remarks – Results The concentration of the test substance at the end of the test was not determined. The test results were based on nominal concentrations. The test substance was observed to adhere to the surfaces of the test containers during the test period. Hence, the reported 96 hours LC50 value may underestimate the toxic effects of the test substance to fish.

CONCLUSION The notified polymer is at least harmful to fish.

TEST FACILITY GmbH (2003a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Product containing the notified polymer

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent Butyldiglycol

Water Hardness Not reported

Analytical Monitoring Not applicable

Remarks - Method Only a study summary was provided. It is unclear whether the test was conducted according to the test guideline.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	-	20	0	0
1		20	1	1
3		20	0	6
5	Not determined	20	0	6
8		20	0	4
10		20	5	12
25		20	10	20
50		20	20	20

EC50 12 mg/L at 48 hours

Remarks - Results The concentrations of the test substance at the end of the test were not determined and the test results were based on nominal concentrations. More than half total number of tested animals (12 out of 20) were observed to be immobilised during 48 hours test period at the 10 mg/L test concentration. The reported 48 hours EC50 = 12 mg/L value may underestimate the toxic effects of the test substance to aquatic invertebrates.

CONCLUSION The notified polymer is at least harmful to aquatic invertebrates.

TEST FACILITY GmbH (2003b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Product containing the notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test - Static

Species *Scenedesmus subspicatus*

Exposure Period 72 hours

Concentration Range	Nominal: Control, 1, 5, 10, 50 and 100 mg/L Actual: Not determined
Auxiliary Solvent	
Water Hardness	Not given
Analytical Monitoring	Not provided
Remarks - Method	The test substance is insoluble in water and butyldiglycol was used as solubiliser. The notified substance was mixed with butyldiglycol and stirred for homogenisation. Water was added to this mixture to make a stock solution.

RESULTS

Growth	
EC50 *mg/L at 72 h*	*NOEC* *mg/L at 72 hours*
> 5	1

Remarks - Results	The concentration of the test substance at the end of the test was not determined and the test results were based on nominal concentrations. During the test, the test substance and algae cells were observed to separate from the test solutions and stick to the glass surfaces. Therefore, the actual concentration of the test substance in the test media may differ with the nominal concentration significantly. At the test concentration of 5 mg/L, there was about 40% inhibition of the algae growth.

CONCLUSION The notified polymer is toxic to algae.

TEST FACILITY GmbH (2003c)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE Product containing the notified polymer + 25% butyldiglycol

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum	Activated sludge
Exposure Period	5 minutes
Concentration Range	Nominal: 10, 100, 250, 500 and 1000 mg/L Actual: Not determined
Remarks – Method	Only the test summary is provided. It is unclear whether there is significant deviation from the test guideline.

RESULTS

EC50	> 1,000 mg/L at 5 min
Remarks – Results	Although no inhibition to bacterial activity was observed, the test was conducted in a 5 minute test period, much shorter than the test period of 0.5–3 hours recommended by the test guideline.

CONCLUSION The notified polymer may not have inhibitory effects to bacterial activity.

TEST FACILITY In-house test

C.2.5. Acute study in earthworm

TEST SUBSTANCE Product containing the notified polymer

METHOD OECD TG 207 Earthworms, Acute toxicity test

Species	*Eisenia Andrei* BOUCHÉ
Exposure Period	14 days
Remarks – Method	The test was conducted according to the test guideline with no significant

deviation from the protocol.

RESULTS

Concentration mg/kg		*Number of Earthworms*	Mortality (%)	
Nominal	*Actual*		*7 Days*	*14 days*
Blank control	-	40	0	0
500	Not determined	40	0	0
1,000		40	0	0
2,000		40	0	0
4,000		40	0	0
8,000		40	0	0

LC50	> 8,000 mg/kg at 14 days
Remarks – Results	No animals of control group showed visible signs of abnormalities. There was no significant change of mean worm weight change at the end of the test.

CONCLUSION Very slightly toxic to earthworm.

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