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March 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Noramine V15

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 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.

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
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
STD/1497	Jotun Australia Pty Ltd	Polymer in Noramine V15	Yes	≤ 20 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 for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Eye Irritant Category 1	H318 – Causes serious eye damage
Skin Sensitiser Category 1	H317 – May cause an allergic skin reaction

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R41: Risk of serious eye damage
R43: May cause sensitisation by skin contact

The environmental hazard classification according to the *Globally Harmonised System for the 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 control measures 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 assessed 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:
  - Eye Irritant Category 1: H318 – Causes serious eye damage
  - Skin Sensitiser Category 1: H317 – May cause an allergic skin reaction

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

Health Surveillance

- As the notified polymer is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

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, automated processes during reformulation, where possible
  - Local exhaust ventilation during reformulation and end-use

- 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 skin and eye contact
  - Avoid inhalation of aerosols/mists

- 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:
  - Coveralls
  - Impervious gloves
  - Eye protection
  - Respiratory protection during spray application

  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, 2012a) or relevant State or Territory Code of Practice.

- A copy of the (M)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 for the 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

- The notified polymer should be disposed of to landfill.

Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012b) or relevant State or Territory Code of Practice.

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(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.

(Material) Safety Data Sheet
The (M)SDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Jotun Australia Pty Ltd (ABN: 29 007 126 696)
9 Cawley Road
BROOKLYN VIC 3012

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, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers/impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Commercial evaluation permit (CEC/818)

NOTIFICATION IN OTHER COUNTRIES
China (2012)
Korea (2013)
Philippines (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Noramine V15 (product containing 50-90% notified polymer in organic solution)

OTHER NAME(S)
Vifa
Aminepoxyadduct (name on MSDS)

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference UV, FTIR and HPLC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow solid flakes

Property	Value	Data Source/Justification
Melting Temperature	45-83 °C	Measured
Boiling Point	Decomposed from 360 °C at 98.0 kPa	Measured
Density	1120 kg/m^3 at 20.9 °C	Measured
Vapour Pressure	5.0 × 10^{-6} kPa at 25 °C	Measured
Water Extractability	0.43-0.57% at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	No hydrolysable functionality.
Partition Coefficient	Not determined	The notified polymer has surface

Property	Value	Data Source/Justification
(n-octanol/water)		activity and is expected to partition to the interface between octanol and water.
Adsorption/Desorption	Not determined	Expected to partition to surfaces from water in the environment based on its surfactant properties and cationic functionalities.
Dissociation Constant	Not determined	The notified polymer contains potential cationic functionalities with a typical pKa ~ 8-11. It is expected to be ionised in the environmental pH range (4-9).
Particle Size	Not tested	Solid flakes with little or no dust
Flammability (Solid)	Not highly flammable	Measured
Autoignition Temperature	No autoignition below melting point	Measured
Explosive Properties	Not explosive	Predicted based on structure
Oxidising Properties	Not oxidising	Predicted based on structure

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

Reactivity
The notified polymer readily reacts with epoxy groups.

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 for the 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 be imported in organic solutions at a concentration of 50-90%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 20	< 20	< 20	< 20	< 20

PORT OF ENTRY
Melbourne, Brisbane, Sydney, Adelaide and Perth.

IDENTITY OF RECIPIENTS
Jotun Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in organic solutions at 50-90% concentration in 200 L closed head steel drums. The steel drums will be palletised and transported by road and stored in a warehouse.

After reformulation, the coating products containing the notified polymer at 25-50% concentration will be filled into 5 L metal containers. The resulting packages will be palletised for storage and transport by road.

USE
The notified polymer will be used as a curing agent for two-part epoxy anticorrosive paints for industrial use.

OPERATION DESCRIPTION
The notified polymer will be formulated in the paint factory into coating component B which will be manually mixed with coating component A before application.

Reformulation
The imported solution (Noramine V15) containing the notified polymer at concentrations of 50-90% will be added to a mixing tank by pouring through a loading hatch. Additional ingredients (solvents and additives) will be added progressively according to the procedures to control the properties of the final mixture. During the process, samples (maximum 1 L) may be taken for quality control purposes. The concentration of the notified polymer in the final mixture will be in the range of 25-50%.

Repackaging
Once approved for packaging, the mixture (the coating component B) will be discharged from the tank through a closed piping system and filled into 5 L metal containers. The resulting packages will be palletised for storage and subsequent transport.

End use
Professional painting contractors will manually mix the coating component B containing the notified polymer with component A before application. The mixed paint containing the notified polymer at 2.5-10% concentration will be predominantly applied by airless spray. A small amount of the paint will also be applied by brush or roller. The surfaces to be painted will be structural steel and associated equipment. The painting process will occur in large open workshops with mechanically assisted ventilation.

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)*
Process operators	2	90
Laboratory personnel	0.5	90
Warehouse workers	2	60
Transport workers	4	60
Painting workers	4	150
Maintenance workers	0.5	60

EXPOSURE DETAILS
Transport and Warehouse
Transport and warehouse workers may come into contact with the notified polymer at concentrations up to 90% as a component of products only in the event of accidental rupture of packaging containers. Personal protective equipment (PPE), such as protective clothing, gloves, safety glasses and boots, used by workers should reduce the chances of accidental exposure.

Reformulation
Process operators adding the solution containing the notified polymer at up to 90% to the mixing tank may have potential for dermal and ocular exposure to the notified polymer. Laboratory personnel may come into contact with the notified polymer at various concentrations up to 90% during quality control analysis. During cleaning process, maintenance workers may have potential for dermal and ocular exposure to residuals of the notified polymer at various concentrations up to 90%.

Dermal and ocular exposure to the above workers should be mitigated through the use of PPE including protective clothing, impervious gloves and safety goggles. Inhalation exposure to the notified polymer is not expected during reformulation given the low vapour pressure of the notified polymer unless aerosols are formed.

End-use
The notifier stated that application of the painting products will occur in large open workshops with appropriate engineering controls such as local enforced ventilation.

There is potential for dermal exposure to the notified polymer at up to 50% concentration when mixing component A with component B containing the notified polymer to form the finished paint.

During spray application of the final painting products, there is a potential for dermal, ocular and inhalation exposure of the workers to the notified polymer at concentrations up to 10%. All workers involved in the spray application of the painting products are expected to wear appropriate PPE including respirators, protective clothing, chemical boots, impervious gloves and safety goggles.

Inhalation exposure to the notified polymer during brush and roller application is not expected given the low vapour pressure of the polymer. The main routes of exposure for the workers during these types of applications will be dermal and ocular.

Once the painting products containing the notified polymer are cured, the polymer will be bound into the matrix of the finished coating and will not be bioavailable for exposure.

6.1.2. Public Exposure

The painting products containing the notified polymer will be used in industrial settings only and will not be available to the public.

The public may come into contact with cured coatings on the surface of the structural steel. However, once cured and dried the notified polymer will be reacted into the coating matrix and will not be available for exposure.

Based on the use pattern, public exposure to the notified polymer is not expected.

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 > 300 mg/kg bw; toxicity inconclusive
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	severely irritating
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOAEL = 225 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* chromosome aberration	non genotoxic

Toxicokinetics

The notified polymer is of low molecular weight (NAMW < 1000 Da), hence the potential for passage across biological membranes cannot be ruled out. However, absorption may be limited by the absence of low molecular weight species < 500 Da and the low water solubility of the notified polymer.

Acute toxicity

An acute oral toxicity study on the notified polymer was provided. However, the highest dose tested in the study was 300 mg/kg bw. The acute toxicity of the notified polymer therefore cannot be determined. Based on the results of this study the potential of the notified polymer to be harmful by the oral route cannot not be ruled out.

Based on the acute dermal toxicity study provided, the notified polymer is of low toxicity via the dermal route.

An acute inhalation toxicity study was not provided. Given the low vapour pressure of the notified polymer inhalation exposure is not expected unless aerosols are formed.

Irritation and sensitisation

Based on the skin irritation study provided, the notified polymer is slightly irritating to the skin. Only very slight oedema and very slight erythema were observed for 2 out of the 3 test animals, with all signs of irritation fully resolved by day 7.

In an eye irritation study conducted with three rabbits, only moderate irritation effects were noted for two of the treated animals which were fully resolved by day 7, whereas the remaining animal displayed severe irritation effects that persisted to the end of the 21 day observation period. However, for the latter animal residual test item was observed in the eye at the 24-hour observation period a small amount of which still remained adhered to the

cornea and lower conjunctival membrane following rinsing with saline. It is therefore postulated by the study authors that the severe irritation effects observed for this animal may not have occurred and would have been in keeping with those observed for the other two treated animals if the test item had been noted in the eye and fully removed at the 1-hour observation period. In the absence of further testing, based on the results of this study the notified polymer is considered severely irritating to the eye.

Based on the results of a skin sensitisation (mouse LLNA) study provided, the notified polymer is considered as a skin sensitiser.

Repeated dose toxicity
In a repeated dose oral toxicity study, the notified polymer was orally administered by gavage at dose levels of 225, 110 and 20 mg/kg bw/day for 28 consecutive days. The results showed treatment-related effects at all dose levels examined. Therefore a No Observed Effect Level (NOEL) could not be established. The study authors stated that the effects detected in the study were mainly due to irritancy of the test substance which was reversible in the recovery period, and therefore the effects detected were not considered to represent an adverse health effect.

Based on the highest dose tested, a No Observed Adverse Effect Level (NOAEL) was established as 225 mg/kg bw/day.

Mutagenicity/Genotoxicity
A bacterial reverse mutation test and an *in vitro* human lymphocyte chromosome aberration test on the notified polymer showed negative results. The notified polymer is not considered to be mutagenic or clastogenic.

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

Hazard classification	*Hazard statement*
Eye Irritant Category 1	H318 – Causes serious eye damage
Skin Sensitiser Category 1	H317 – May cause an allergic skin reaction

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R41: Risk of serious eye damage
R43: May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer is severely irritating to the eye, slightly irritating to the skin and a skin sensitiser. Its potential to be harmful by the oral route cannot be ruled out. Toxicity by the inhalation route is not known.

Reformulation workers may be exposed (dermal and ocular) to the notified polymer at up to 90% concentration. Inhalation exposure is only expected if aerosols are formed. At these concentrations, workers could be at risk of irritation and sensitisation effects. The stated use of engineering controls (enclosed processes and local exhaust ventilation) and personal protective equipment (skin and eye protection) during reformulation is expected to minimise exposure and reduce the risk of such effects.

During end-use, professional painters may be exposed (dermal and ocular) to the notified polymer at up to 50% concentration when mixing the two components to form the finished paint. At these concentrations, workers could be at risk of irritation and sensitisation effects. The stated use of personal protective equipment (skin and eye protection) by these workers is expected to minimise exposure and reduce the risk of such effects.

When applying the finished paints containing the notified polymer at up to 10% concentration there is potential for dermal, ocular and inhalation exposure. At these concentrations, workers could be at risk of eye irritation and sensitisation effects, and possibly adverse effects from inhalation. The stated use of personal protective

equipment (skin, eye and respiratory protection during spray application) by these workers is expected to minimise exposure and reduce the risk of such effects. Furthermore spray applications are expected to occur in well-ventilated areas that should further minimise inhalation exposure.

Provided the stated control measures above are in place to minimise worker exposure to the notified polymer, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer is intended for use in industrial applications only. The public may come into contact with metal objects treated with the products containing the notified polymer. However, the notified polymer will be reacted into the coating matrix and will not be bioavailable for exposure after the coatings are cured.

Therefore, when used in the proposed manner, the risk to public health from 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 release of the notified polymer to the environment during importation, storage, and transport is unlikely. Release during reformulation in Australia is expected to arise from spills, formulation equipment cleaning and residues in import containers. Accidental spills during transport or reformulation are expected to be captured in a solvent. The solvent is recycled with residue being disposed of to landfill. Import containers will either be recycled or disposed of through an approved waste management facility. Less than 2% of the import volume is estimated to be released to landfill as a result of reformulation in Australia.

RELEASE OF CHEMICAL FROM USE

During application by spray, it is expected that up to 10% of the notified polymer will be released as overspray, which will be collected and disposed of to landfill. Residues containing the notified polymer on brushes and rollers are expected to be rinsed into containers and then allowed to cure before disposal, as solid wastes, to landfill. Less than 5% of the notified polymer may remain as residues in product containers and these will be disposed of to landfill or recycled. Equipment used to apply the coating formulations may be rinsed with solvent. The solvent is expected to be recycled with residue being disposed of to landfill. It is estimated that less than 1% of the import volume of the notified polymer will be collected from cleaning of equipment, which is expected to be treated and disposed of by a licensed waste contractor.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will be cured into an inert matrix with other chemical substances as part of the coating process and hence will be immobilised within a polymeric film on coated articles. The notified polymer incorporated in the coating with the coated articles, at the end of their useful life, are expected to either go to metal recyclers or be disposed of to landfill.

7.1.2. Environmental Fate

The notified polymer was determined not to be readily biodegradable (0% biodegradability over 28 days). For the details of the environmental fate study please refer to Appendix C.

When used as one component of a two-part system for industrial coating of steel, the majority of the notified polymer is expected to cross-link to form an inert polymer film after its application. The notified polymer will share the fate of the coated articles, which are expected to be eventually disposed of to landfill or be subjected to metal reclamation. In its cured form, the notified polymer is not expected to be bioavailable or mobile in the environment. Bioaccumulation of the uncured polymer is unlikely due to the limited bioavailability and surface activity of the notified polymer. The notified polymer will eventually degrade in landfill via biotic or abiotic pathways, or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is not expected to be present at significant concentrations in the aquatic environment because of the very low potential for direct release to surface waters when used in steel coating for industrial applications. A Predicted Environmental Concentration (PEC) has therefore not been calculated.

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	*Result (mg/L)*	*Assessment Conclusion*
Fish Toxicity	LL50 (96 h) = 7.9 (WAF)*	Toxic to fish
Daphnia Toxicity	EL50 (48 h) = 5.7 (WAF)*	Toxic to aquatic invertebrates
Algal Toxicity	E_rL50 (72 h) = 8.1 (WAF)* NOEL (72 h) = 1.0	Toxic to algae
Inhibition of Bacterial Respiration	EC50 (3 h) = > 1000 mg/L (loading)	Not inhibitory to bacterial respiration

WAF*= Water Accommodated Fraction

Based on the endpoints for fish, Daphnia and algal toxicity, the notified polymer is considered to be toxic to aquatic organisms on an acute basis, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009). Therefore, the notified polymer is formally classified as "Acute Category 2; Toxic to aquatic life" under the GHS. Based on the acute toxicity and potential for the notified polymer to persist in the environment, the chronic hazard of the notified polymer has been 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) for the notified polymer has been calculated and is presented in the table below. The PNEC is calculated based on the endpoint of the most sensitive species (Daphnia, 48 h EL50 = 5.7 mg/L). An assessment factor of 100 has been used as acute toxicity endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EL50 (Invertebrates)	5.7	mg/L
Assessment Factor	100	
PNEC:	57	µg/L

7.3. Environmental Risk Assessment

A Risk Quotient is unable to be quantified as a PEC was not calculated. There is no significant aquatic release of the notified polymer anticipated based on its reported use pattern. Moreover, after curing, the majority of the imported quantity of the notified polymer will be irreversibly incorporated into an inert matrix and it is not expected to be mobile, bioavailable or bioaccumulative. Uncured polymer waste is not expected to bioaccumulate in biota based on the notified polymer's surface activity. On the basis of the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Temperature 45-83 °C

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	Determined using a modified capillary method/melting temperature device with liquid bath.
Test Facility	Harlan (2012a)

Boiling Point Decomposed from approximately 360 °C at 98.0 kPa

Method	OECD TG 103 Boiling Point. EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks	Determined by differential calorimetry. The test substance decomposed from approximately 360 °C and no boiling point could be determined.
Test Facility	Harlan (2012a)

Density 1120 kg/m^3 at 20.9 °C

Method	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	Determined using a gas comparison pycnometer.
Test Facility	Harlan (2012a)

Vapour Pressure 5.0×10^{-6} kPa at 25 °C

Method	OECD TG 104 Vapour Pressure. EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	Determined using the vapour pressure balance method. The vapour pressure was determined through 7 individual tests. The test substance did not change in appearance under the conditions used.
Test Facility	Harlan (2012b)

Water Extractability 0.43-0.57% at 20 °C

Method	OECD TG 120 Solution/Extraction Behaviour of Polymers in Water (Flask Method).
Remarks	The results indicate that the water extractability of the notified polymer is loading rate dependent. The concentration of organic carbon dissolved in the sample solutions was determined by Total Organic Carbon (TOC) Analysis at a pH range of 7.7-9.5.
Test Facility	Harlan (2012a)

Partition Coefficient

Method	In house method
Remarks	The test substance was shaken with an equal amount of water saturated with n-octanol. It was observed that the two immiscible phases emulsified easily; additionally, after 1 hour standing, there were still three phases, a translucent, upper layer, a white, frothy, middle layer and a cloudy lower layer. It was therefore considered that the test substance was surface-active.
Test Facility	Harlan (2012a)

Particle Size Not tested

Method	OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.
Remarks	The test substance consisted of relatively large yellow solid flakes with little or no dust. Test of particle size was considered unnecessary.
Test Facility	Harlan (2012a)

Flammability (Solids) Not highly flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks	The test substance failed to ignite during 2 minutes under Bunsen flame.
Test Facility	Harlan (2012c)

Autoignition Temperature No autoignition below melting point

Method	EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks	No exothermic reaction/self-heating of the test substance was observed during the test.
Test Facility	Harlan (2012c)

Explosive Properties Predicted not explosive

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	The structure of the test substance was assessed for chemical groups that imply explosive properties and no structure alert was noted.
Test Facility	Harlan (2012c)

Oxidizing Properties Predicted not oxidising

Method	EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids).
Remarks	The structure of the test substance was assessed for chemical groups that imply oxidising properties and no structure alert was noted.
Test Facility	Harlan (2012c)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Procedure. EC Council Regulation No 440/2008 B.1 bis Acute toxicity (oral) fixed dose method.
Species/Strain	Rat/Wistar (RccHan™:WIST)
Vehicle	Polyethylene glycol 400
Remarks - Method	The notified polymer was found to be unsuitable for dosing in the vehicle at a dose level of 2000 mg/kg bw. The highest dose level tested was 300 mg/kg bw.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	1 F	300	0/1
2	4 F	300	0/4

LD50	> 300 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	The LD50 was estimated based on the highest dose tested. No evidence of systemic toxicity via oral route for the notified polymer was noted at the dose level of 300 mg/kg bw.
CONCLUSION	Based on the results of this study, the acute oral toxicity of the notified polymer cannot be determined but is at most harmful by the oral route.
TEST FACILITY	Harlan (2013a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Wistar (RccHan™:WIST)
Vehicle	Dimethyl sulphoxide (DMSO)
Type of dressing	Semi-occlusive
Remarks - Method	Solid flakes of the notified polymer were moistened with DMSO and administered to the treatment sites.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M	2000	0/5
2	5 F	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Yellow coloured staining and skin irritation signs were noted.
Signs of Toxicity - Systemic	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	Skin irritation signs noted included slight erythema, glossy skin, various

scabs and crust formation.

CONCLUSION The notified polymer is of low toxicity via the dermal route.

TEST FACILITY Harlan (2012i)

B.3. 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	Rabbit/New Zealand White
Number of Animals	Three
Vehicle	The test substance was ground to a powder and moistened sufficiently with distilled water in order to from a paste prior to application.
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviation. An *ex vivo* pre-screen test, the Transcutaneous Electrical Resistance (TER) Assay, was performed prior to the *in vivo* skin irritation test which indicated that the test substance was unlikely to be corrosive to the skin.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	1	1	1	< 7 days	0
Oedema	0	0.7	0.3	1	< 72 h	0

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

Remarks - Results Very slight oedema and very slight erythema was observed for 2 of the test animals. All signs of irritation were fully resolved by day 7. No evidence of skin irritation was observed in one test animal.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY Harlan (2012j)

B.4. 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).

Species/Strain	Rabbit/New Zealand White
Number of Animals	Three
Observation Period	21 days
Remarks - Method	No significant protocol deviation.

Due to the high pH of the notified chemical, a rabbit enucleated eye test was performed prior to the *in vivo* test which indicated that the test substance was unlikely to cause severe ocular irritancy.

The test substance was ground to a powder prior to application. Approximately 92 mg of the test substance at a volume of 0.1 mL was administered to each test site.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.7	2	1.3	2	> 21 days	2
Conjunctiva: chemosis	0.3	3	1	3	> 21 days	2
Conjunctiva: discharge	0.3	2	0	2	> 21 days	2
Corneal opacity	0	2	0	2	> 21 days	2
Iridial inflammation	0	1	0	1	> 21 days	1

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

Remarks - Results

For two of the tested animals mild to moderate conjunctival irritation was observed. Iridial inflammation was also observed for one of these animals at the 1 hour observation period only. All signs of irritation for these two animals were fully resolved by day 7.

For the remaining animal, irritation effects included translucent corneal opacity, iridial inflammation and moderate conjunctival irritation. Other effects noted were a pale area of the nictitating membrane, alopecia, vascularisation of the cornea and slightly raised cornea resulting in a slightly conical appearance of the eye. The irritation effects of this animal still persisted at the end of the 21 day observation period. However, for this animal residual test item was observed in the eye at the 24-hour observation period a small amount of which still remained adhered to the cornea and lower conjunctival membrane following rinsing with saline. It is therefore postulated by the study authors that the severe irritation effects observed for this animal may not have occurred and would have been in keeping with those observed for the other two treated animals if the test item had been noted in the eye and fully removed at the 1-hour observation period.

In the absence of further testing, based on the results of this study the notified polymer is considered to be severely irritating to the eye.

CONCLUSION The notified polymer is severely irritating to the eye.

TEST FACILITY Harlan (2013b)

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

TEST SUBSTANCE Notified polymer

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EU Commission Regulation No. 440/2008 B.42 Skin Sensitisation (Local Lymph Node Assay)

Species/Strain Mouse/CBA/CaOlaHsd

Vehicle Dimethyl formamide (DMF)

Remarks - Method No significant protocol deviation. Positive control study was conducted separately using 15% α-hexylcinnamaldehyde in DMF.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	1535.27	1
5	5385.87	3.51
10	6810.81	4.44

25	6704.15	4.37
Positive Control		
15	-	5.74

Remarks - Results: No signs of systemic toxicity of the test substance were noted during the test.

CONCLUSION: There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.

TEST FACILITY: Harlan (2012k)

B.6. Repeat dose toxicity

TEST SUBSTANCE: Notified polymer

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

Species/Strain: Rat/Wistar Han™:RccHan™:WIST
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 28 days
Dose regimen: 7 days per week
Post-exposure observation period: 14 days
Vehicle: Polyethylene glycol 400
Remarks - Method: Groups dosed with vehicle only and at 225 mg/kg bw/day (highest dose tested) were utilised as recovery groups and maintained without treatment for a further 14 days after the treatment.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
Control	10 (5 M/5 F)	0	0/10
Low dose	10 (5 M/5 F)	20	0/10
Mid dose	10 (5 M/5 F)	110	0/10
High dose	10 (5 M/5 F)	225	0/10
Control recovery	10 (5 M/5 F)	0	0/10
High dose recovery	10 (5 M/5 F)	225	0/10

Mortality and Time to Death
No unscheduled deaths attributable to treatment with the test substance were noted.

Clinical Observations
Isolated instances of increased salivation and noisy respiration were noted for animals treated at 225 and 110 mg/kg bw/day. One animal treated at 225 mg/kg bw/day showed hunched posture with laboured and decreased respiration on Day 28 of treatment and Day 1 of recovery. Slight increase of water consumption in animals treated at 225 mg/kg bw/day was also noted.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Male rats treated at 225 mg/kg bw/day showed an increase in white blood cell counts specifically in the lymphocyte fraction, a reduction in bilirubin values, an increase in aspartate aminotransferase and a reduction in creatinine levels.

Females in 225 mg/kg bw/day group showed reductions in cholesterol levels and alkaline phosphatase levels. These females also showed an increase in urine volume with reduced specific gravity.

Animals of either sex treated at 225 mg/kg bw/day and males treated at 110 mg/kg bw/day showed an increase in blood urea levels. Bile acids were reduced for animals of either sex treated at 225 and 110 mg/kg bw/day.

Triglycerides were reduced for animals of either sex treated at 225 mg/kg bw/day with the effect extending into the males treated at 110 and 20 mg/kg bw/day. This effect was still evident following the recovery period with

animals treated at 225 mg/kg bw/day.

Effects in Organs

Males treated at 225 mg/kg bw/day showed slight increases in adrenal and kidney weights. Minimal or mild mucosal hyperplasia was present in the intestines of both sexes treated at 225 mg/kg bw/day. An increase in the number of syncytial macrophages was noted in the mesenteric lymph nodes of the animals treated at 225 and 110 mg/kg bw/day. Minimal or mild focal spongiosis, characterised by vacuolation of squamous epithelial cells in the region of the limiting ridge of the stomach, was observed in several animals of both sexes treated at various doses and one male in the control group.

Remarks – Results

Due to the effects observed at all dose levels, a No Observed Effect Level (NOEL) could not be established. The study authors stated that the effects detected in the study were mainly due to irritancy which were seen to be reversible following the cessation of the treatment, and therefore the effects detected were not considered to represent an adverse health effect.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 225 mg/kg bw/day in this study, based on the highest dose tested.

TEST FACILITY Harlan (2013c)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer

METHOD

	OECD TG 471 Bacterial Reverse Mutation Test. EU Commission Regulation No. 440/2008 B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure and Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98 and TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Phenobarbitone/β-naphthoflavone induced rat liver microsomal enzyme fraction (S9)
Concentration Range in Main Test	With/without metabolic activation: *E. coli* - 0.15-500 µg/plate *S. typhimurium* - 0.15-150 µg/plate
Vehicle	DMSO
Remarks - Method	No significant protocol deviations.
	Positive controls: *E. coli* WP2uvrA – 2 µg/plate N-ethyl-N'-nitro-N-nitrosoguanidine (ENNG) *S. typhimurium* TA1535 – 5 µg/plate ENNG TA1537 – 80 µg/plate 9-aminoacridine (9AA) TA98 – 0.2 µg/plate 4-nitroquinoline-1-oxide (4NQO) TA100 – 3 µg/plate ENNG

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 50	≥ 50	> 500	Negative
Test 2	-	≥ 15	> 150	Negative

Present				
Test 1	≥ 150	≥ 50	> 500	Negative
Test 2	-	> 50	> 150	Negative

Remarks - Results

A light test substance precipitate (particulate in appearance) was noted only at 5000 µg/plate in the preliminary test.

No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.

All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Harlan (2012l)

B.8. Genotoxicity – *in vitro*

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test.
EC Regulation No. 440/2008 B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test.

Species/Strain: Human cells
Cell Type/Cell Line: Lymphocytes
Metabolic Activation System: Phenobarbitone/β-naphthoflavone induced rat liver microsomal enzyme fraction (S9)
Vehicle: DMSO
Remarks - Method: No significant protocol deviation.

Positive controls:
Without metabolic activation – mitomycin C (MMC)
With metabolic activation – cyclophosphamide (CP)

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 2, 4, 8*, 16*, 24, 32*	4 h	24 h
Test 2	0*, 4, 8, 16*, 32*, 64*, 80	24 h	24 h
Present			
Test 1	0*, 4*, 8*, 16*, 32*, 48, 64	4 h	24 h
Test 2	0*, 4, 8*, 16*, 32*, 48, 64	4 h	24 h

*Cultures selected for metaphase analysis.

RESULTS

Haemolysis was noted at the end of the exposure at concentrations ≥ 16 µg/mL in the absence of metabolic activation and at concentrations ≥ 32 µg/mL in the presence of metabolic activation.

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 19.53	≥ 32	> 32	Negative
Test 2	≥ 19.53	≥ 64	≥ 32	Negative
Present				
Test 1	≥ 39.06	≥ 32	≥ 32	Negative

Test 2	-	≥ 32	≥ 32	Negative

Remarks - Results	The test substance did not induce statistically significant increase in the frequency of cells with chromosome aberration in either the absence or the presence of metabolic activation.
CONCLUSION	The notified polymer was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.
TEST FACILITY	Harlan (2012m)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Carbon dioxide and Total Organic Carbon (TOC) Analysis
Remarks – Method	The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	0	2	43
8	0	8	61
14	0	14	65
21	0	21	65
28	0	28	74
29*	0	29	61

* Day 29 values corrected to include any carry-over of CO_2 detected in the replicate

Remarks - Results	All validity criteria for the test were satisfied. The toxicity control attained 26% degradation after 14 days and 30% after 28 days, indicating the test substance was not toxic to the micro-organisms in the sewage treatment sludge used in the test.
CONCLUSION	The notified polymer is not considered to be readily biodegradable.
TEST FACILITY	Harlan (2012d)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-Static.
Species	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	140 mg $CaCO_3$/L
Analytical Monitoring	Total Organic Carbon (TOC) Analysis.
Remarks – Method	Due to the low aqueous solubility and complex nature of the test item for the purposes of the range-finding test the test item was prepared as a Water Accommodated Fraction (WAF). The test substance was ground using a pestle and mortar. Amounts of test substance (21, 37.8, 67.2 and 210 mg) was each separately added to 21 litres of dechlorinated tap water to give 1.0, 1.8, 3.2, 5.6 and 10 mg/L loading rates respectively. The mixtures were stirred for 23 hours and allowed to stand for 1 hour. The Water Accommodated Fraction (WAF) was obtained by mid-depth siphoning followed by filtering through a glass

wool plug.

The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Concentration mg/L Nominal Loading Rate WAF	*Number of Fish*	*Mortality*				
		3h	*24 h*	*48 h*	*72 h*	*96 h*
Control	7	0	0	0	0	0
1.0	7	0	0	0	0	0
1.8	7	0	0	0	0	0
3.2	7	0	0	0	0	0
5.6	7	0	0	0	0	0
10	7	0	0	0	0	6

LL50	7.9 mg/L at 96 hours WAF (95% confidence limit: 7.1-8.7 mg/L).
NOEL	5.6 mg/L at 96 hours WAF
Remarks – Results	All validity criteria for the test were satisfied.

Sub-lethal effects of exposure were observed at the 10 mg/L WAF. These responses included the fish being static at the base of the vessel and swimming at the water surface. After approximately 72 hours exposure 6 out of 7 fish at 10 mg/L WAF were observed to exhibit prolonged sub-lethal effects.

Given that the toxicity cannot be attributed to a single component or a mixture of components, but to the test substance as a whole, and the dissolved test substance was at or below the quantifiable limit of the analytical method, the results were based on nominal loading rates only.

CONCLUSION The notified polymer is toxic to fish

TEST FACILITY Harlan (2012e)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Total Organic Carbon (TOC) Analysis
Remarks - Method	Due to the low aqueous solubility and complex nature of the test item for the purposes of the range-finding test the test item was prepared as a Water Accommodated Fraction (WAF).

The test substance was ground using a pestle and mortar. An amount of test substance (100 mg) was added to the surface of 10 litres of culture medium to give 10 mg/L loading rate. After the addition the mixture was stirred by magnetic stirrer. The stirring was stopped after 23 hours and the mixture was allowed to stand for 1 hour. The Water Accommodated Fraction (WAF) was obtained by mid-depth siphoning followed by filtering through a glass wool plug. A series of dilutions was made from the 10 mg/L to give stock solutions of 0.1, 0.32, 1.0 and 3.2 mg/L WAF.

The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Concentration mg/L Nominal Loading Rate WAF	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
Control	20	0	0
0.1	20	0	0
0.32	20	0	0
1.0	20	0	0
3.2	20	0	1
10	20	10	19

EL50	5.7 mg/L at 48 hours WAF (95% confidence limits: 4.4 -7.2 mg/L).
NOEL	1.0 mg/L at 48 hours WAF.
Remarks - Results	All validity criteria for the test were satisfied. Given that the toxicity cannot be attributed to a single component or a mixture of components, but to the test substance as a whole, and the dissolved test substance was at or below the quantifiable limit of the analytical method, the results were based on nominal loading rates only.

CONCLUSION The notified polymer is toxic to aquatic invertebrates

TEST FACILITY Harlan (2012f)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Council Regulation No 440/2008 C.3 Algal Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal loading rates of 0.032, 0.10, 0.32, 1.0 and 3.2 mg/L.
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Total Organic Carbon (TOC) Analysis.
Remarks - Method	The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed. The test substance was ground using a pestle and mortar. An amount of test substance (100 mg) was added to the surface of 10 litres of culture medium to give 10 mg/L loading rate. After the addition the mixture was stirred by magnetic stirrer. The stirring was stopped after 23 hours and the mixture was allowed to stand for 1 hour. The Water Accommodated Fraction (WAF) was obtained by mid-depth siphoning followed by filtering through a glass wool plug. A series of dilutions was made from the 10 mg/L to give stock solutions of 0.032, 0.1, 0.32, 1.0 and 3.2 mg/L WAF.

RESULTS

Biomass		*Growth*	
E_yL50 mg/L at 72h (WAF)	*NOEL mg/L*	*E_rL50 mg/L at 72 h (WAF)*	*NOEL mg/L*
2.8	1.0	8.1*	1.0

* The endpoint was extrapolated as no loading rate tested resulted in greater than 50% inhibition of growth rate.

Remarks - Results	All validity criteria for the test were satisfied. Given that the toxicity cannot be attributed to a single component or a

	mixture of components, but to the test substance as a whole, and the dissolved test substance was at or below the quantifiable limit of the analytical method, the results were based on nominal loading rates only.
CONCLUSION	The notified chemical is toxic to algae.
TEST FACILITY	Harlan (2012g)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: Dispersion of the test substance at 10, 100 and 1000 mg/L.
Remarks – Method	The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed. Activated sewage sludge was exposed to a dispersion of the test item at a loading rate of 10, 100 and 1000 mg/L for a period of 3 hours at a temperature of 20 ± 2 °C with the addition of a synthetic sewage as a respiratory substrate.
RESULTS	All validity criteria for the test were satisfied.
EL50	> 1000 mg/L
NOEL	1000 mg/L
Remarks – Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration
TEST FACILITY	Harlan (2012h)

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