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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Tolonate X FLO 100

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
STD/1600	Ixom Operations Pty Ltd	Tolonate X FLO 100	Yes	≤ 20 tonnes per annum	Component of industrial paints and coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

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*
Skin Sensitisation (Category 1)	H317 – May cause an allergic skin reaction

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

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

Environmental risk assessment
On the basis of the 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:
  - Skin Sensitisation (Category 1): H317 – May cause an allergic skin reaction

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

Health Surveillance

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

CONTROL MEASURES

Occupational Health and Safety

- 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:
  - Ensure good general ventilation during application of paints and coatings

- Avoid inhalation of vapours, mists and aerosols
- Avoid skin and eye contact
- Clean up spills promptly
- The Safe Work Australia exposure standard for isocyanates of 0.02 mg/m^3 (TWA) and 0.07 mg/m^3 (STEL) should be observed (SWA, 2013)

- A person conducting a business or undertaking at a workplace should implement the following safe engineering controls to minimise occupational exposure during handling of the notified polymer:
  - Ventilation system, including local exhaust ventilation during reformulation
  - Ventilated spray booths during spray application, where applicable
  - Spray application to occur in well-ventilated areas when spray booths cannot be used

- 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:
  - Impervious gloves
  - Safety glasses
  - Coveralls
  - Respiratory protection if inhalation exposure may occur

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for Spray Painting and Powder Coating (SWA, 2015a) or relevant State or Territory Code of Practice.

- Where good general ventilation is inadequate, and inhalation exposure may occur, atmospheric monitoring should be conducted to measure workplace concentrations of isocyanates during use of products containing the notified polymers. A person conducting a business or undertaking should ensure that the exposure standard for isocyanates (SWA, 2013) is not exceeded for all areas where the notified polymer may be handled or present.

- 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.

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

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 component of industrial coating, 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.

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

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ixom Operations Pty Ltd (ABN: 51 600 546 512)
Level 8, 1 Nicholson Street
EAST MELBOURNE VIC 3002

NOTIFICATION CATEGORY
Standard: Synthetic polymer with Mn < 1,000 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, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: melting point/boiling point, vapour pressure, water solubility, hydrolysis as a function of pH, partition coefficient, dissociation constant, particle size, flammability limits, autoignition temperature, explosive properties, oxidising properties and reactivity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME
Tolonate X FLO 100

MOLECULAR WEIGHT
500–1,000 Da

ANALYTICAL DATA
Reference NMR, IR HPLC, GC, UV and GPC were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 ºC and 101.3 kPa: clear liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Thermally stable up to 250 ºC	Measured
Boiling Point	> 250 °C at 133 kPa	SDS
Density	1,041 kg/m^3 at 25.1 °C	Measured
Vapour Pressure	Not determined	Expected to be low
Water Extractability	< 2%	Measured
Hydrolysis as a Function of	Not determined	Contains groups that readily react with

pH		water to yield products that could undergo further reactions to form insoluble higher molecular weight polymers.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to react with water to form carbon dioxide and insoluble high molecular weight polymers.
Adsorption/Desorption	Not determined	Expected to bind to negatively charged soil or sediment as the notified polymer contains potential cationic groups.
Dissociation Constant	Not determined	The notified polymer contains potential cationic functionalities and is likely to be ionised.
Flash Point	199 °C at 102.5 kPa	Measured
Autoignition Temperature	Not determined	-
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 storage. The notified polymer will react with alcohols, acids, alkalis and amines. The notified polymer rapidly reacts with water to form an insoluble urea and carbon dioxide.

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 be imported as neat notified polymer (i.e. at ≤ 100% concentration).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	3	10	10	20	20

PORT OF ENTRY
Brisbane, Sydney or Melbourne

IDENTITY OF RECIPIENTS
IXOM Operations Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported by sea (mixed full container load or less than container load) in sealed 215 kg closed head steel drums and transported to warehouses by road. Formulated coatings in 4 L, 10 L and 20 L cans will be transported by road throughout Australia.

USE
The notified polymer (at 20–50% concentration) will be used as a part of two component paints and other coatings for concrete surfaces (including garage floors, balconies, furniture and decorative floors), timber flooring (commercial and residential) and anti-corrosion coatings on metal.

It is expected that 5% of the total Australian introduction volume will be to light industrial markets, 80% to commercial markets and 15% to residential markets.

OPERATION DESCRIPTION

The notified polymer will be reformulated into paint and other coating products at the customer's manufacturing sites. Reformulation process involve manual transfer of notified polymer using drum hoist and pouring directly into the mixing vessel or by metered dosing using metering pump to mixing sealed vessel. The vessel is fitted with high speed mixer and local exhaust ventilation system. The mixed paints and coatings are filtered and then transferred into 4 L, 10 L and 20 L cans under exhaust ventilation.

The end use customer will mix or blend the formulation containing the notified polymer (20–50% concentration) with the second part of the coating using a spatula or volumetric pump. The final formulation (≤ 25% concentration) will be applied on materials, typically over a primer. Polysaspartic floor coatings (e.g. garage floors) and moisture cure polyurethane applications (timber or concrete substrates) will be applied to surfaces by brush or roller. Other surfaces may be coated by spray, which is expected to be < 5% of the market. The applied coating may be heat-cured (at less than 80 ºC) or air-dried to aid the solvent evaporation and the crosslinking reactions between resin and the notified polymer.

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 storage	< 4	< 220
Reformulation workers	< 4	< 220
Professional painters	< 8	< 220

EXPOSURE DETAILS

Transport and warehouse workers

Transport and storage workers are not expected to be exposed to the notified polymer (at ≤ 100% concentration) except in the unlikely event of an accident. The storage facilities are classified as major hazard facilities or manifest quantity dangerous goods locations.

Reformulation

Reformulation workers may be exposed (by dermal and ocular routes) to the notified polymer at ≤ 100% concentration when during transferring the notified polymer to the blending tank, during blending and during quality control testing. The reformulation workers may also be exposed to the notified polymer at 20–50% concentration during filling the finished product into containers.

The reformulation and filling process will take place in areas which are equipped with local exhaust ventilation. Dermal and ocular exposure of the notified polymer to workers should be mitigated through the use of personal protective equipment (PPE) including coveralls, impervious gloves and safety glasses.

Maintenance workers and cleaners

Dermal and ocular exposure to the notified polymer may occur during maintenance and cleaning process. Dermal and ocular exposure should be mitigated through the use of coveralls, safety glasses and gloves.

End-users

Professional painters may be exposed to the product containing the notified polymer (at 20–50% concentration) by the dermal and ocular routes while opening the containers, mixing with the second component of the coating system, applying the coatings and cleaning equipment. Inhalation exposure to the notified polymer may occur if applied by spray.

Dermal and ocular exposure should be mitigated through the use of PPE including coveralls, gloves and goggles. In addition, inhalation exposure should be minimised by the use of respiratory protection.

After application and once cured, the notified polymer is not expected to be bioavailable, and further dermal contact should not lead to exposure.

6.1.2. Public Exposure

The products containing the notified polymer will only be used by professionals and will not be sold to the public. The general public may also come into contact with paints containing the notified polymer after application to surfaces. However, once the coatings are dried, the notified polymer will be bound within a matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer and an analogue 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 > 2,000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	not conclusive
Skin irritation (in vitro)	non-corrosive and non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay (LLNA)	evidence of sensitisation
Rat, repeat dose inhalation toxicity – 90 days*	NOAEL = 3.3 mg/m^3 air
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro gene mutation test in CHO Cells (HPRT Locuas Assay)*	non genotoxic
Genotoxicity – in vitro Chromosome Aberration Assay in V79 Cells*	non genotoxic

* Test conducted on an analogue polymer. The analogue polymer submitted by the notifier is a polymeric form of one of monomer constituents of the polymer. The monomer contains free isocyanate, the functional group concern in the notified polymer, and it also contains a similar branched structure and molecular weight (±20%) to the notified polymer. The analogue polymer is considered to represent the worst-case scenario for the notified polymer for the toxicological endpoints submitted.

Toxicokinetics, metabolism and distribution

The notified polymer has a molecular weight < 1,000 Da and contains a significant proportion of low molecular weight species (i.e. < 500 Da), hence absorption across biological membranes cannot be ruled out. However, absorption may be limited as the notified polymer in contact with water will from carbon dioxide and insoluble inert polyurea compounds.

Acute toxicity

The notified polymer was found to be of low acute toxicity via the oral route based on a test conducted in rats. In an acute inhalation sighting study conducted in rats, no conclusive outcome could be drawn due to the small sample size. The authors conducted the study to determine the validity of self-classification of the chemical as Acute Inhalation Toxicity (Category 4) and Single Target Organ Toxicity (Category 3). The potential for the notified polymer to be harmful by inhalation and cause respiratory irritation cannot be ruled out.

Irritation and sensitisation

The notified polymer contains isocyanate functional groups that are of concern for irritation, dermal and respiratory sensitisation, and pulmonary toxicity (Barratt, 1994; Kirk-Othmer, 1995; SWA, 2015b; US EPA 2010). As there is presently not a reliable animal model for testing diisocyanates for potential respiratory sensitisation, the US EPA assume that all diisocyanates may be potential human respiratory sensitisers. It has also been reported that isocyanates may also cause respiratory sensitisation by skin contact (US EPA, 2010).

Polymeric isocyanates are less volatile and contain less free isocyanate, and are therefore expected to be less of an inhalation hazard. However, the UK Employment Medical Advisory Service believes polymeric isocyanate aerosols are capable of causing respiratory sensitisation similarly to monomer vapours, and reports have shown that inhalation of relatively non-volatile isocyanates in the form of dusts and spray-mists could cause adverse respiratory effects (SWA, 2015b).

The notified polymer was found to be non-corrosive and non-irritating to the skin in an in vitro test. The notified polymer was found to be slightly irritating to the eye of rabbits.

In an LLNA study in mice, there was evidence of induction of a lymphocyte proliferative response indicative of strong skin sensitisation to the notified polymer with an EC3 value of 0.759%.

Repeated dose toxicity
A NOAEL of 3.3 mg/m^3 air for Wistar rats was established for the analogue polymer conducted according to OECD TG 413. Inflammatory changes in the lower respiratory tract were noted at the 26.4 mg/m^3 dose level.

Mutagenicity/Genotoxicity
The notified polymer was not mutagenic in a bacterial reverse mutation (AMES) test. Based on two vitro genotoxicity studies on the analogue polymer, the notified polymer was not considered to be genotoxic.

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 table below.

Hazard classification	***Hazard statement***
Skin Sensitisation (Category 1)	H317 – May cause an allergic skin reaction

In addition to the above classification, the notified polymer is classified by the notifier as follows:

Hazard classification	***Hazard statement***
Acute inhalation toxicity (Category 4)	H332 – Harmful if inhaled
Specific target organ toxicity (Category 3)	H335 – May cause respiratory irritation

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Reformulation workers will handle the notified polymer in a neat form (≤ 100% concentration). The notified polymer has been classified by the notifier as harmful by inhalation and may cause respiratory irritation. Based on the studies provided, the notified polymer is slightly irritating to the eyes and may cause a skin sensitisation.

Inhalation exposure of workers to the notified polymer may occur, particularly inhalation of aerosols of the notified polymer (≤ 25% concentration) during end-use spray applications. Spray application is expected to take place in well-ventilated areas with respiratory protection to minimise the potential for inhalation exposure.

Airborne concentrations of isocyanates should be kept below the exposure standard set by Safe Work Australia in all areas where spray operations occur (SWA, 2013). Where respiratory protection is deemed to be appropriate, it should consist of an appropriately fitted and maintained air-line respirator or self-contained breathing apparatus complying with the relevant Australian Standard.

Irritation and sensitisation may occur as a result of dermal exposure to the notified polymer at concentrations of ≤ 100% during reformulation and ≤ 50% during end-use. Dermal exposure is expected to be minimised by the wearing of personal protective equipment by workers, including gloves, goggles, and coveralls.

The risk to workers associated with exposure to the notified polymer is not considered unreasonable, provided that the stated engineering controls, 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 come into contact with surfaces coated with products containing the notified polymer (≤ 25% concentration) when it is trapped within a cured polymer matrix and, therefore, is not expected to be bioavailable for exposure.

However, the public may come into contact with the uncured notified polymer (at 20–50% concentration) if safe work practices are not followed by end-use workers in public settings (e.g. garages). Provided that workers use the stated safe work practices and PPE during the use of the notified polymer, 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 not expected excepting accident spillage. Accidental spills containing the notified polymer are expected to be contained and absorbed into inert materials and be collected into suitable containers for safely disposal by a licensed waste disposal contractor.

Spills, leaks and washings for equipment cleaning during reformulation processes are expected to account for up to 1% of the total import volume of the notified polymer. These wastes are expected to be collected and disposed of with a licenced waste disposal contractor. It is estimated that up to 1% of the notified polymer may remain in empty drums. The empty drums containing residual notified polymer are expected to be disposed of to landfill via a licensed waste disposal contractor.

RELEASE OF CHEMICAL FROM USE

The final formulation containing the notified polymer will be used for coating concrete, furniture based on concrete and decorative floors using rollers, brushes or spray guns. The majority of the coatings containing the notified polymer will form inert polymer matrix adhering to the articles to which it is applied.

The release as overspray during use will typically entail landfill disposal, after interception by spray booth filters. Brushers and rollers used for coating may be rinsed with solvent. Wastes from cleaning of brushes and rollers are expected to be disposed of via a licensed waste disposal 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. The cured coating is expected to remain in place on the coated structure for its operational life unless damaged. The polymer incorporated in this coating will ultimately either be removed by abrasive or disposed of along with the surfaces, which will be disposed of to landfill. Abrasively removed coating is expected to be collected and disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted. The notified polymer is expected to rapidly hydrolyse and degrade based on its structure and functional groups.

The majority of the notified polymer is expected to be cured into polymeric matrix as part of its use in coating systems on concrete or timber. The notified polymer is irreversibly bound into the matrix and is not expected to be bioavailable or bioaccumulate. The notified polymer in solid waste disposed of to landfill, is not expected to be mobile and is expected to degrade by biotic and abiotic processes to form water and oxides of carbon and nitrogen.

Based on its use pattern, significant amount of the notified polymer is 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 partition from water column to sediment as it reacts rapidly with water to form carbon dioxide and insoluble inert polymerised compounds.

The notified polymer is expected to hydrolyse rapidly to yield products that are expected to undergo further reactions to form insoluble high molecular weight species.

The notified polymer has a number average molecular weight < 1,000 Da and significant percentage of low molecular weight constituents. Thus, the notified polymer is likely to cross biological membranes. However, the

notified polymer is expected to undergo rapid reactions in water and form high molecular weight species, which reduces the bioaccumulation potential.

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 polymerised compounds. Further, aquatic exposure of the notified polymer is not expected based on the reported use pattern.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The notified polymer contains functionality that has the potential to be toxic to aquatic life. Ecotoxicological endpoints for the notified polymer were calculated based on Structure-Activity Relationship (SAR) equations assuming a worst case cationic charge density for the polymer (Boethling and Nabholz, 1997). The endpoints are summarised in the table below and have been modified by mitigation factors to account for the anticipated binding of the polymer with organic carbon in surface waters.

Endpoint	Result	Assessment Conclusion
Fish Toxicity	LC50 (96 h) = 0.28 mg/L	Very toxic to fish
Daphnia Toxicity	EC50 (48 h) = 0.10 mg/L	Very toxic to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 0.04 mg/L	Very toxic to algae

The notified polymer is potentially very toxic to aquatic organisms based on the above SAR results. The QSAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

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

A Risk Quotient was not quantified as a PEC and PNEC were not calculated. The reported use pattern of the notified polymer indicates that there is no significant anticipated aquatic release. Moreover, after curing, the majority of notified polymer will be incorporated into an inert matrix with other chemicals and is not expected to be mobile or bioavailable. Hence, the environmental exposure is not expected to be significant. 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

Density 1.041 kg/m^3 at 25.1 °C

METHOD	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	
TEST FACILITY	Vencorex

Water Extractability < 2%

METHOD	In-house test
Remarks	Flask Method
TEST FACILITY	Canadian Assessment report

Appendix B: Toxicological Investigations

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar (RccHan:WIST)
Vehicle	None
Remarks - Method	GLP Certificate. Minor deviation did not affect the validity of the study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 F	2,000	0
2	3 F	2,000	0

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No clinical signs were noted during the study.
Effects in Organs	No macroscopic findings were noted in the animals at the end of observation period.
Remarks - Results	The mean body weight increased all animals.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	TNO Triskelion (2012a)

B.2. Acute toxicity – inhalation

TEST SUBSTANCE	Notified polymer
METHOD	Sighting study for OECD TG 403 Acute Inhalation Toxicity – Limit Test.
Species/Strain	Rat/Crl:CD(SD)
Vehicle	None
Method of Exposure	Snout-only exposure
Exposure Period	4 hours
Physical Form	Liquid aerosol
Particle Size	Mass median aerodynamic diameter = 2.2 μm and geometric standard deviation = 1.96
Remarks - Method	GLP Certificate. No protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Concentration (mg/L)*		*Mortality*
		Nominal	*Actual*	
1	1 per sex	2.47	0.963 ± 0.0501	0/2

LC50	Not determined
Signs of Toxicity	Treatment related clinical signs of fast, irregular, shallow and laboured breathing and piloerection indicated that the test substance was irritating. These signs were evident during exposure for both animals, with clinical signs persisting until day 5 in the female rat. Body weight losses of 22 g and 19 g, for the male and female respectively, were observed on the day following the exposure. This was considered by the study authors to be a consequence of the restriction to food and water

due to the method of restraint, and partly due to the clinical condition of the animals. Recovery of body weight losses was made by day 4 for the male and day 8 for the female, with gains continuing for the remainder of the study.

Effects in Organs: In consideration of the small group size in the study, firm conclusions on microscopic findings could not be made. Therefore, findings of an uncertain relationship to treatment were seen in the lungs and bronchi (foamy alveolar macrophages) of both animals and tracheobronchial lymph node (increased germinal centre development and increased cellularity of the paracortex) of the female animal. The presence of foamy alveolar macrophages in both animals correlated with macroscopic findings of pale areas in the lungs.

The enlargement of the tracheobronchial lymph node recorded at necropsy for the female animal was accounted for by the increased germinal centre development and increased cellularity of the paracortex.

Remarks - Results: Both animals survived the treatment and the 14 day observation period, showing reversibility of adverse clinical signs and recovery of initial body weight losses.

CONCLUSION: The notified polymer may be harmful via inhalation and may cause respiratory irritation.

TEST FACILITY: Huntingdon Life Sciences (2014)

B.3. Irritation – skin (in vitro)

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 431 In vitro Skin Corrosion - Human Skin Model Test
OECD TG 439 In vitro Skin Irritation: Reconstructed Human Epidermis Test Method

Vehicle: None

Remarks - Method: GLP Certificate.
Minor deviation did not affect the validity of the study.

RESULTS

In vitro skin corrosion test

Test material	Mean OD570 of triplicate tissues	Relative mean Viability (%)	SD of relative mean viability
Negative control	1.847	0.192	100 ± 10
Test substance	1.759	0.104	95 ± 6
Positive control	0.222	0.034	12 ± 2

OD = optical density; SD = standard deviation

In vitro skin irritation test

Test material	Mean OD570 of triplicate tissues	Relative mean Viability (%)	SD of relative mean viability
Negative control	2.085	0.067	100 ± 3
Test substance	2.144	0.175	103 ± 8
Positive control	0.150	0.003	7 ± 0

OD = optical density; SD = standard deviation

Remarks - Results: *In vitro skin corrosion test*
Optical density of the negative control (Milli-Q) and positive control (8 M KOH) were within the acceptance ranges and correctly indicated non corrosivity and corrosivity respectively. In the range of between 20% and 100% mean tissue viability the SD was ≤ 30%. Therefore the study was considered valid.

In vitro skin irritation test
Optical density of the negative control (phosphate buffered saline) and positive control (5% aqueous sodium dodecyl sulphate) were within the acceptance ranges and correctly indicated non irritancy and irritancy respectively. In the range of between 20% and 100% mean tissue viability the SD was < 18%. Therefore the study was considered valid.

CONCLUSION The notified polymer was non-corrosive and non-irritating to the skin under the conditions of the test.

TEST FACILITY TNO Triskelion (2012b)

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).
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 F
Observation Period	72 hours
Remarks - Method	GLP Certificate. No protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.3	0.3	0.3	1	< 48 h	0
Conjunctiva: chemosis	0	0	0	1	< 24 h	0
Conjunctiva: discharge	0.3	0.3	0.3	1	< 48 h	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results At 1 hour after treatment, slight redness and swelling of conjunctivae were observed in all rabbits. At 24 hours after treatment, slight redness of conjunctivae and slight ocular discharge were observed in all rabbits. At 48 and 72 hours after treatment, all effects disappeared.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY TNO Triskelion (2012c)

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

TEST SUBSTANCE Notified polymer

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay

Species/Strain	Mouse/
Vehicle	Acetone/Olive Oil(4/1; v/v)
Preliminary study	Yes
Positive control	α-hexyl cinnamaldehyde (HCA)
Remarks - Method	GLP Certificate. As increase of ear thickness higher than 25% (i.e., around 30%) was observed from the concentration of 10%, the highest concentration retained for the main test was therefore set at 5%.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	4 F	119.88	-
0.25	4 F	130.13	1.09
0.5	4 F	174.25	1.45
1	4 F	532.38	4.44
2.5	4 F	2,826.63	23.58
5	4 F	5,360.88	44.72
Positive Control			
25	4 F	1,387.63	11.58

EC3	0.759%
Remarks - Results	A significant dose-related lymphoproliferation was noted. In the absence of significant local irritation at all test concentrations (i.e., increase in ear thickness < 25%), the significant lymphoproliferative response at these concentrations was attributed to delayed contact hypersensitivity. No unscheduled deaths and no clinical signs were observed during the observation period. Body weight of animals was not affected by the test substance treatment. At 5%, dryness of ear skin was observed in all females on day 6. A mean increase of ear thickness of 12.17% was recorded between days 1 and 6, showing a slightly irritant effect of the test substance. No sign of irritancy was noted in other groups. The positive control group showed SI of 11.58, higher than the threshold positive value of 3. Therefore the experiment was considered valid.
CONCLUSION	There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.
TEST FACILITY	CiToxLAB France (2013)

B.6. 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
Species/Strain	S. typhimurium: TA1535, TA1537, TA98, TA100 E. coli: WP2uvrA
Metabolic Activation System	A liver fraction of Aroclor 1254-induced rats for metabolic activation (S9-mix).
Concentration Range in Main Test	Test 1 with and without metabolic activation: 0, 62, 185, 556, 2,667 and 5,000 µg/plate Test 2 with and without metabolic activation: 0, 12.3, 37, 111, 333 and 1,000 µg/plate for TA1535, TA98, TA100 and WP2uvrA Test 2 with and without metabolic activation: 0, 4.1, 12.3, 37, 111 and 333 µg/plate for TA 1537
Vehicle	Dimethylsulphoxide (DMSO)
Remarks - Method	GLP Certificate. No preliminary test was conducted.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥ 556	> 1,667	negative
Test 2	≥ 1,000	> 1,000	negative
Present			
Test 1	≥ 556	> 1,667	negative
Test 2	≥ 1,000	> 1,000	negative

Remarks - Results

In the first test, the mean numbers of his+ and trp+ revertant colonies of the negative controls in all strains used were within the acceptance range. In the second test, the mean numbers of his+ and trp+ revertant colonies of the negative controls in all strains used were within the acceptance range, except for the the negative control for strain WP2uvrA. The number of revertants was just above the acceptable range; the possible occurrence of slight deviations from the acceptance criteria described in the study plan was considered by study authors to be acceptable and not influence the outcome of the study. In both tests, in all strains the positive controls showed the expected increase in the mean numbers of revertant colonies.

In the first test, the test substance was toxic to all strains, in both the absence and presence of S9-mix at various concentrations. Toxicity was shown by a decrease in the mean number of revertants and/or a (slight) less dense background lawn of bacterial growth and pinpoint colonies. As a result, in several strains, in both absence and presence of S-9 mix, less than three non-toxic concentrations were tested which is considered to be the minimum for a valid test result. In all strains only 2 non-precipitating concentrations were tested. Therefore a second test was performed.

In the first test, in all strains, in both the absence and presence of S9-mix, the test substance did not induce a more than 2-fold and/or dose related increase in the mean number of revertant colonies compared to the background spontaneous reversion rate observed with the negative control.

In the second test, the test substance was toxic to all strains, in both the absence and presence of S9-mix at various concentrations. Toxicity was shown by a decrease in the mean number of revertants and/or a (slight) less dense background lawn of bacterial growth. For all strains, in both the absence and presence of S9-mix, three or more non-toxic concentrations could be evaluated.

In the second test, in strain TA 1537, in the presence of S-9 mix, a 2.4 fold increase was observed at 37 µg/plate. As this increase was not dose related, noted at a single concentration and not reproducible at a slightly higher non-toxic concentration of 62 µg/plate in the first test, the increase was considered not biologically relevant. In all other strains, in both absence and presence of S9-mix the test substance did not induce a more than 2-fold and/or dose related increase in the mean number of revertant colonies compared to the background spontaneous reversion rate observed with the negative control.

In both tests, in all strains tested, a dose related precipitation of the test substance was observed on the agar plates and in the final treatment mix, in both the absence and presence of S9-mix. In the first test the precipitation was observed on the agar plates at and above 1,667 µg/plate and in the final treatment mix at and above 556 µg/plate and in the second test on the agar plates and in the final treatment at 1,000 µg/plate. This precipitation did not interfere with counting revertants.

CONCLUSION

The notified polymer was not mutagenic to bacteria under the conditions

of the test.

TEST FACILITY TNO Triskelion (2012d)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
EC Directive 2000/32/EC B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.

Species/Strain	Chinese hamster
Cell Type/Cell Line	HPRT locus in V79 cells
Metabolic Activation System	S9 fraction from Aroclor 1254-induced rat liver
Vehicle	Dimethylsulfoxide (DMSO)
Remarks - Method	GLP Certificate. No protocol deviations.

Metabolic Activation	Test Substance Concentration (µg/mL)	Exposure Period	Expression Time	Selection Time
Absent				
Test 1	0*, 1.5*, 3.0*, 6.0*, 12.0*, 18.0*, 24.0*	4 h	6-8 d	7 d
Test 2	0*, 2.5*, 5.0*, 7.5*, 10.0*, 15.5*, 20.0	4 h	6-8 d	7 d
Present				
Test 1	0*, 0.2*, 0.4*, 0.8*, 1.6*, 3.2*, 6.4*	4 h	6-8 d	7 d
Test 2	0*, 0.25*, 0.50*, 1.00*, 2.00*, 4.00*, 6.00*	4 h	6-8 d	7 d

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/mL) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent	≥ 10			
Test 1		≥ 12.0	> 24.0	negative
Test 2		≥ 7.5	> 20.0	negative
Present	≥ 5			
Test 1		≥ 3.2	> 6.4	negative
Test 2		≥ 6.00	> 6.00	negative

Remarks - Results The test substance did not lead to a statistically significant increase in the number of mutant revertant colonies either in the presence or absence of S9 mix. The mutant frequencies at any concentration were within the range of the concurrent vehicle control and the historical negative control data.

The increase in the frequencies of mutant colonies induced by the positive control demonstrated the sensitivity of the test method and the metabolic activity of the S9 mix.

CONCLUSION The analogue polymer was not clastogenic to CHO Cells treated in vitro under the conditions of the test.

TEST FACILITY BASF (2007a)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian

	Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	V79 cells
Metabolic Activation System	S9 fraction from Aroclor 1254-induced rat liver
Vehicle	Dimethylsulfoxide (DMSO)
Remarks - Method	GLP Certificate. No protocol deviations.

Metabolic Activation	Test Substance Concentration (µg/mL)	Exposure Period	Harvest Time
Absent			
Test 1	0, 3.1, 6.3*, 12.5*, 25*, 50, 100	4 h	18 h
Test 2	0, 6.3, 12.5, 25*, 50*, 100*, 200	18 h	18 h
Test 3	0, 25, 50, 100*, 200	18 h	28 h
Present			
Test 1	0, 3.1, 6.3*, 12.5*, 25*, 50, 100	4 h	18 h
Test 2	0, 3.1, 6.3, 12.5*, 25*, 50*, 100	4 h	28 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/mL) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent	≥ 50			
Test 1		≥ 25	> 100	negative
Test 2		≥ 200	> 200	negative
Test 3		≥ 100	> 200	negative
Present	≥ 50			
Test 1		≥ 50	> 100	negative
Test 2		≥ 50	> 100	negative

Remarks - Results

The test substance did not cause any increase in the number of structurally aberrant metaphases including and excluding gaps at both sampling times either in the absence or presence of S9 mix. No increase in the frequency of cells containing numerical chromosome aberrations was noted.

The positive and vehicle controls gave satisfactory responses confirming the validity of the test system.

CONCLUSION

The analogue polymer was not clastogenic to V79 Cells treated in vitro under the conditions of the test.

TEST FACILITY

BASF (2007b)

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