

File No: LTD/1976

August 2018

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

PUBLIC REPORT

Dispersogen PL 30

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

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

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**Director
NICNAS**

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1976	Clariant (Australia) Pty Ltd	Dispersogen PL 30	ND*	≤ 3 tonnes per annum	Dispersing agent in water-based pigment preparations

* ND: not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation:
 - Use of enclosed/automated systems
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling and end use of the notified polymer:
 - Avoid eye contact
 - Avoid inhalation of aerosols or spray
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation and end use:
 - Protective clothing
 - Impervious gloves
 - Goggles
 - 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, 2015)* or relevant State or Territory Code of Practice.

- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

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

Emergency procedures

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

Regulatory Obligations

Secondary Notification

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

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

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1,000 g/mol;
 - the notified polymer is present at > 1% concentration in end use products.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a dispersing agent in water-based pigment preparations, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

Safety Data Sheet

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)
 Level 3 Olympus Building
 3 Acacia Place
 296 – 324 Ferntree Gully Road
 NOTTING HILL VIC 3168

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ g/mol

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 and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation of the scheduled data requirements is being claimed for all physical chemical properties except for melting point and water solubility.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME

Dispersogen PL 30

OTHER NAME

Dispersogen PSL 100

MOLECULAR WEIGHT

Number Average Molecular Weight (M_n) is $> 1,000$ g/mol.

ANALYTICAL DATA

Reference GPC and FTIR spectra were provided.

3. COMPOSITION

Degree of Purity

$> 98\%$

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless, slightly turbid, viscous liquid

Property	Value	Data Source/Justification
Melting Point	12 ± 3 °C	Measured
Boiling Point	Not determined	Decomposes at approximately 290 °C (SDS)
Density	1,080 kg/m ³ at 25 °C	SDS
Vapour Pressure	$< 1 \times 10^{-6}$ kPa at 25 °C	Calculated
Water Solubility	$> 1,000$ g/L at 20 °C	Measured

Property	Value	Data Source/Justification
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities but significant hydrolysis is not expected in the environmental pH range of 4 – 9
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition from n-octanol to water based on its high water solubility
Adsorption/Desorption	Not determined	Not expected to bind strongly to soils and sediments based on its high water solubility
Dissociation Constant	Not determined	Does not contain dissociable functionality
Flash Point	136 °C (Closed Cup)	SDS
Flammability	Not determined	–
Autoignition Temperature	395 °C	SDS
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES

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

Reactivity

The notified polymer is expected to be stable under normal conditions of use. It is susceptible to biodegradation in the environment.

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. The notified polymer will be imported neat as the product Dispersogen PL 30 or in pigment preparations at concentrations $\leq 10\%$. Local reformulation of Dispersogen PL 30 or pigment preparations will occur at various sites.

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

Year	1	2	3	4	5
Tonnes	≤ 2	≤ 2	≤ 3	≤ 3	≤ 3

PORT OF ENTRY

Melbourne or Sydney

TRANSPORTATION AND PACKAGING

The notified polymer in neat form or in pigment preparations (at $\leq 10\%$ concentration) will be imported in 60 L drums and distributed to industrial customers. The notified polymer or products containing the notified polymer will be stored in tightly sealed drums at facilities of Clariant (Australia) Pty Ltd and then distributed to industrial customers by road and rail.

USE

The notified polymer will be used as a dispersing agent at $\leq 10\%$ concentration in water-based pigment preparations. The primary use of the notified polymer will be in water-based paints. Finished paint products containing the notified polymer will be used by both industrial and do-it-yourself (DIY) users. The pigment preparations containing the notified polymer may also be added into mixtures for tyre, rubber or plastic manufacturing.

The pigment preparations containing the notified polymer at $\leq 10\%$ concentration may be added to waterborne paints at a maximum concentration of 10%. Therefore, the final use concentration of the notified polymer in finished products will be $\leq 1\%$.

OPERATION DESCRIPTION

Manufacture of the notified chemical will not occur in Australia.

*Reformulation/repackaging*Pigment Preparations

The notified polymer (imported as Dispersogen PL 30) will be reformulated at industrial customer sites into pigment preparations at $\leq 10\%$ concentrations. At the reformulation sites, factory workers will be involved in transferring the notified polymer from imported containers (60 L drums) into blending tanks by manual pouring or other mechanical methods. The blending processes will involve high-shear force mixing. The reformulated pigment preparations will be packed into drums for distribution to downstream industrial customers or end users.

Paints

The pigment preparations containing the notified polymer (at $\leq 10\%$ concentration) will further be reformulated into paint products. Blending of paint formulations will occur at industrial customer facilities. This will involve the pigment preparations being manually transferred or pumped directly from storage drums into mixing tanks. High speed mixing will be used to blend the paint components. During mixing, the tanks will be in an enclosed environment under local exhaust ventilation. The finished paint products containing the notified polymer (at $\leq 1\%$ concentration) will be filled from floor pots via hoppers into 1 – 20 L paint containers by gravity feed. The filling lines will be equipped with ventilation extraction systems.

Quality assurance (QA) personnel will take samples and test the final paint formulations containing the notified polymer in a laboratory.

End use

Finished paint products containing the notified polymer (at $\leq 1\%$ concentration) can be applied by brush, roller or spray mainly by professional painters. Spray applications will generally be conducted in spray booths where overspray and volatile materials will be collected using protective materials and filtering systems.

6. HUMAN HEALTH IMPLICATIONS**6.1. Exposure Assessment****6.1.1. Occupational Exposure**

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	8	200
Blending, coating and quality controls	4	200
Coating application	8	200

EXPOSURE DETAILS

Transport and Storage

Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident as the notified polymer and the products containing the notified polymer will be sealed in containers during transport and storage. Workers are expected to wear appropriate personal protective equipment (PPE) including coveralls, gloves and boots.

Reformulation

During reformulation operations, dermal and ocular exposure of workers to the notified polymer in neat form is possible when weighing and transferring of the notified polymer from imported containers into blending tanks. Inhalation of the notified polymer is not expected unless the polymer becomes airborne. The notifier stated that PPE, such as coveralls, gloves, suitable respirators, and eye protection will be used when handling the notified polymer. During filling operations, potential exposure of workers to the notified polymer in pigment preparations (at $\leq 10\%$ concentration) and in finished paint products (at $\leq 1\%$ concentration) will likely be through dermal or ocular routes. The exposure is expected to be minimised using automated/enclosed systems and appropriate PPE.

Members of QA staff will wear laboratory coats, gloves and safety glasses to minimise exposure to the notified polymer in the samples during testing.

End use

For professional workers using the finished paint products, dermal, ocular or inhalation exposure to the notified polymer (at $\leq 1\%$ concentration) will most likely occur during applications of the products to surfaces using spray, brushes or rollers. Dermal and ocular exposure can also occur from spills during opening, decanting and mixing processes of the paint products, and during equipment cleaning. Inhalation exposure to the notified polymer at $\leq 1\%$ concentration is possible when spray applications are used. As advised by the notifier, most spray applications will occur in spray booths to reduce the exposure to aerosolised notified polymer. The notifier also proposed the use of suitable respirators during spray applications. Other PPE including protective clothing, safety boots, impervious gloves and safety goggles are also proposed for end users.

6.1.2. Public Exposure

DIY users may come into contact with the notified polymer (at $\leq 1\%$ concentration) when using the finished paint products. The exposure pattern of these DIY users is expected to be similar to that described above for professional workers. However, the frequency and extent of exposure is expected to be lower compared to workers. Certain level of PPE may be used by DIY users. By following the safe use instructions provided with the paint products, the potential for exposure to the notified polymer is expected to be further reduced.

Members of the public may come into contact with surfaces coated with the finished paint products containing the notified polymer. However, once dried the notified polymer is expected to be bound into the inert matrix of the paints and will not be available for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating

Toxicokinetics, metabolism and distribution

No information on the toxicokinetics, metabolism and distribution of the notified polymer was provided. Based on the high molecular weight of the notified polymer ($M_n > 1,000$ g/mol) it is not expected to be readily absorbed across biological membranes.

Acute toxicity

The notified polymer was found to have low acute oral toxicity in rats.

No information on acute dermal or acute inhalation toxicity was provided.

Irritation

In a skin irritation study conducted in rabbits, the notified polymer did not produce irritating effects.

The eye irritation study submitted for the notified polymer showed slight to moderate reddening of the conjunctivae in rabbits 1 hour after the treatment. Slight reddening of the sclerae was also present. The redness was reverted to normal within 72 hours. In addition, slight ocular discharge was recorded at the 1 hour observation. The notified polymer was considered to be slightly irritating to the eyes.

Sensitisation

No information on skin sensitisation was provided. There were no structural alerts identified in the notified polymer indicative of sensitisation potential.

Health hazard classification

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Reformulation workers may come into dermal contact with the notified polymer in neat form when handling it. Slight eye irritation effects may be possible if eye protection is not used. The notifier stated in the application that the use of appropriate PPE including skin and eye protections is expected to minimise the exposure. In addition, the risk of any adverse effects will be further minimised if enclosed and automated processes are used during reformulation.

Professional painters may be exposed to the notified polymer at $\leq 1\%$ concentration via dermal, ocular and inhalation routes during application of paints by brush, roller and spray. No data are provided for dermal and inhalation toxicity of the notified polymer. However, given the relatively low concentration of the notified polymer in paint products and the expected use of spray booths and appropriate PPE including respiratory protection during spray application, the risk to the health of professional painters from use of the notified polymer is not considered to be unreasonable.

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

Similar to professional painters, DIY users may come into contact with the notified polymer at $\leq 1\%$ concentration via dermal, ocular and inhalation routes during application of paints by brush, roller or spray. Given that the paints contain a relatively low concentration of the notified polymer and the paint products will be used less frequently and in much smaller scales by DIY users compared to professional users, the extent of exposure is expected to be low. Therefore, risk to the health of DIY users from the use of the notified polymer is not considered to be unreasonable.

Members of the public may come into contact with articles or surfaces which have been treated with paints or coatings containing the notified polymer. However, the notified polymer will be bound within an inert matrix and will not be available for further exposure.

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported in pigment preparations at concentrations $\leq 10\%$, or in neat form as the product Dispersogen PL 30 for local reformulation into the pigment preparations at $\leq 10\%$ concentration. The pigment preparations containing the notified polymer will be further reformulated into paint products. The reformulation processes involve blending operations which will occur in an enclosed environment under local exhaust ventilation. Wastes containing the notified polymer generated from the reformulation processes are expected to be disposed of in accordance with local government regulations. Accidental spills of the notified polymer during import, reformulation, transport or storage are expected to be adsorbed onto suitable materials and collected for disposal in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The pigment preparations containing the notified polymer may be added to water-based paints resulting in a final use concentration of $\leq 1\%$ for the notified polymer. The pigment preparations may also be added into mixtures for tyre, rubber or plastic manufacturing.

The primary use of the notified polymer will be in water-based paints. Finished paint products containing the notified polymer will be used by both industrial and do-it-yourself (DIY) users, and will be applied by brush, roller or spray to a range of substrates such as wood, concrete or metal. As estimated by the notifier, up to 30% of the paints in professional use could be lost as overspray, which would be captured by the spray booths and be

disposed of to landfill in accordance with local government regulations. The waste from cleaning of the professional application equipment is expected to be collected by an approved waste management facility, and be disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified polymer is expected to share the fate of the substrates to which it has been applied, either subjected to metal reclamation or being disposed of to landfill at the end of their useful lives. Used tyres, rubber and plastic materials containing the notified polymer may enter recycling streams, but they will ultimately end up in landfill. The notifier estimated that < 1% of the import volume of the notified polymer may remain as residual in empty containers which is expected to be cured into an inert solid matrix and be disposed of in accordance with local government regulations. As the worst case scenario, it is assumed that up to 5% of the paints containing the notified polymer used by DIY users may be incorrectly disposed of to the sewers, drains, or ground from waste and washing of application equipment. As most of the pigment preparations containing the notified polymer will be used in paints and a significant proportion may be used by DIY users, it is assumed for the worst-case that 5% of the notified polymer will be released to sewer.

7.1.2. Environmental Fate

During metal reclamation, the notified polymer will thermally decompose to form water vapour and oxides of carbon and sulphur. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile.

A biodegradation test conducted on the notified polymer (100% degradation in 28 days) indicates that the notified polymer is likely readily biodegradable. Therefore, the small portion of the notified polymer that is incorrectly disposed of to sewers by DIY users is expected to be removed effectively through biodegradation at sewage treatment plants (STPs) before potentially being released to surface waters.

The notified polymer is not expected to be bioaccumulative due to its high molecular weight. In landfill, soil, sludge and water, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and sulphur.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the predicted environmental concentration (PEC) is summarised in the table below. Based on the worst-case scenario, a conservative release of 5% of the annual import volume to sewers on a nationwide basis over 365 days per year is used for the notified polymer. It is also assumed under the worst-case scenario that there is no removal of the notified polymer during sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment

Total Annual Import/Manufactured Volume	3,000	kg/year
Proportion expected to be released to sewer	5	%
Annual quantity of chemical released to sewer	150	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.41	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0%	
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.08	µg/L
PEC - Ocean:	0.01	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (with density of 1,500 kg/m³). Using these assumptions, irrigation with a concentration of 0.08 µg/L may potentially result in a soil concentration of approximately 0.56 µg/kg. Based on the potential biodegradability of the notified polymer, annual accumulation is not expected.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of the study can be found in Appendix C.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	96 h EC50 > 100 mg/L	Not harmful to fish

As only one ecotoxicological endpoint was provided and it indicates that the notifier polymer is not expected to be harmful to fish, the notified polymer was provisionally not classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The conservative predicted no-effects concentration (PNEC) has been calculated based on the endpoint for fish as shown in the table below. A conservative safety factor of 1,000 was used given the acute endpoint for only one trophic level is available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
96 h EC50 for fish	> 100 mg/L
Assessment Factor	1,000
Mitigation Factor	1.00
PNEC:	> 100 µg/L

7.3. Environmental Risk Assessment

The Risk Quotient ($Q = PEC/PNEC$) has been calculated based on the PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.08	100	< 0.01
Q - Ocean	0.01	100	< 0.01

The conservative risk quotients ($Q = PEC/PNEC$) for the worst-case discharge scenario have been calculated to be much less than 1 for both riverine and ocean compartments indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its annual importation quantity and use pattern. Therefore, based on the calculated risk quotient, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Melting Point** $12 \pm 3 \text{ }^\circ\text{C}$

Method OECD TG 102 Melting Point/Melting Range
EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature
Remarks Pour Point Method was used
Test Facility Clariant (2016a)

Vapour Pressure $< 1 \times 10^{-6} \text{ kPa at } 25 \text{ }^\circ\text{C}$

Method MPBPWin v1.43 software (Syracuse Research Corp)
MPBPWIN Version 1.43/Syracuse from EPI Suite by U.S. Environmental Protection
Agency (EPA) Office of Pollution Prevention Toxics and Syracuse Research Corporation
(SRC)
Remarks Calculated from molecular structure
Test Facility Clariant (2018)

Water Solubility $> 1,000 \text{ g/L at } 20 \text{ }^\circ\text{C}$

Method OECD TG 105 Water Solubility
Remarks Flask method
Test Facility Clariant (2016b)

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

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/HanRcc:WIST (SPF)
Vehicle	Purified water
Remarks - Method	No major deviations from the test guideline were reported.

RESULTS

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

LD50 > 2,000 mg/kg bw
Signs of Toxicity Slightly ruffled fur was observed in all treated females 2 – 3 hours post dosage and persisted up to 5 hours in 2 females.

Effects in Organs No other clinical signs were observed.
Remarks - Results No abnormalities were observed at necropsy.
All animals survived until scheduled necropsy and showed expected body weight gain during the observation period.

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

TEST FACILITY RCC (2008a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation)
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (1 M/2 F)
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	Test substance was used as supplied.

No major deviations from the test guideline were reported.

RESULTS

Remarks - Results Under the study conditions, a single dermal application dose of 0.5 mL of the notified chemical to 1 male and 2 female rabbits showed no clinical signs of corrosive or irritation effects.

No mortalities or other significant clinical signs of toxicity were observed.

CONCLUSION The notified polymer is not irritating to the skin.

TEST FACILITY RCC (2008b)

B.3. Irritation – eye

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation)
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (1 M/2 F)
Observation Period	72 hours
Remarks - Method	Test substance was used as supplied.

No major deviations from the test guideline were reported.

RESULTS

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

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

Remarks - Results No abnormal findings were observed in the cornea or iris of any animal at any of the measurement intervals.

A slight to moderate reddening of the conjunctivae was noted in all 3 animals 1 hour after instillation and persisted as slight reddening up to 48 hour observation. A slight reddening of the sclerae was present in 2 animals (1 M and 1 F) at 1 hour post treatment. In addition, slight ocular discharge was recorded in both females at the 1 hour observation.

No abnormal findings were observed in the treated eye of any animal 72 hours after treatment.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY RCC (2008c)

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 from a local STP
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	CO ₂ by titrimetric method
Remarks - Method	No major deviations from the test guidelines were reported. The test substance was directly added to the test vessels. A toxicity control was run.

RESULTS

Day	<i>Test substance</i>		<i>Sodium benzoate</i>	
	Day	% Degradation	Day	% Degradation
6		19	6	66
15		47	15	96
21		68	21	100
28		100	28	100

Remarks - Results All validity criteria for the test were satisfied. The percentage degradation of the reference compound, sodium benzoate surpassed the threshold level of 60% within 14 days indicating the suitability of the inoculums. The toxicity control exceeded 25% biodegradation after 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after 28 days was 100%. Although the 10 day window in replicate 1 started a week after replicate 2, both replicates passed the 10 day window.

CONCLUSION The test substance is readily biodegradable.

TEST FACILITY Dr U Noack-Laboratorien (2008)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	<i>Danio rerio</i>
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	59 mg CaCO ₃ /L
Analytical Monitoring	None
Remarks – Method	A limit test was run with no significant deviations from the test guidelines reported. The test substance was directly added to the test vessels.

RESULTS

<i>Concentration (mg/L)</i>		<i>Number of Fish</i>	<i>Mortality 96 h</i>
<i>Nominal</i>	<i>Actual</i>		
Control	Control	7	0
100	Not determined	7	0

LC50	> 100 mg/L at 96 hours
Remarks – Results	All validity criteria for the test were satisfied. The dissolved oxygen concentration in the test solution during the test was $\geq 97\%$.
CONCLUSION	The test substance is not harmful to fish.
TEST FACILITY	Dr U Noack-Laboratorien (2007)

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