File No: LTD/2030

May 2018

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Poly(oxy-1,2-ethanediyl), α,α'-(3-carboxy-3-hydroxy-1,5-dioxo-1,5-pentanediyl)bis[ω-hydroxy-, di-C_{9-11}-isoalkyl ethers, C_{10}-rich

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/2030	BASF Australia Ltd	Poly(oxy-1,2-ethanediyl), α,α'-(3-carboxy-3-hydroxy-1,5-dioxo-1,5-pentanediyl)bis[ω-hydroxy-, di-C_{9-11}-isoalkyl ethers, C_{10}-rich	Yes	≤ 30 tonnes per annum	Component of industrial paints and 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 of 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*
Skin irritation (Category 2)	H315: Causes skin irritation
Serious eye damage (Category 1)	H318: Causes serious eye damage

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 assumed low hazard and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Skin irritation (Category 2): H315 – Causes skin irritation
  - Serious eye irritation (Category 1): H318 – Causes serious eye damage

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

Safety Data Sheet

- The SDS for the product containing the notified polymer should be amended to include the hazardous information of the notified polymer as follows:
  - Classified as Category 1 Serious eye damage/Irreversible effects on the eye (H318 - Causes serious eye damage)

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:
  - Automated and enclosed systems during reformation and packaging
  - Spray booth during spray application
  - Local exhaust ventilation if formation of mist or aerosol is expected during reformulation and use

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer during reformulation and use:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosols or 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 during reformulation and use:
  - Impervious gloves
  - Protective clothing
  - Eye protection
  - Respiratory protection if aerosols are generated or 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.

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, 2012) 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(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1,000 g/mol;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of industrial paints and 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.

Safety Data Sheet
The SDS of the product containing 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)
BASF Australia Ltd (ABN: 62 008 437 867)
Level 12
28 Freshwater Place
SOUTHBANK VIC 3006

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 g/mol

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: other names, 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 claimed for all physical and chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China (2015)
Korea (2014)
Japan (2015)
New Zealand (2017)

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Poly(oxy-1,2-ethanediyl), α,α'-(3-carboxy-3-hydroxy-1,5-dioxo-1,5-pentanediyl)bis[ω-hydroxy-, di-C_{9-11}-isoalkyl ethers, C_{10}-rich

CAS NUMBER
1630821-44-1

MARKETING NAME(S)
Dispex® Ultra PX 4525 (imported product containing the notified polymer at ≤ 70%)

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) is > 1,000 g/mol

ANALYTICAL DATA
Reference IR and GPC spectra were provided

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Red to brown liquid*

Property	Value	Data Source/Justification
Freezing Point	-20 °C*	SDS
Boiling Point	> 100 °C at 101.3 kPa*	SDS

Density	1,090 kg/m^3 at 20 °C*	SDS
Vapour Pressure	< 2.3 kPa at 20 °C*	SDS
Water Solubility	Soluble	SDS
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups but significant hydrolysis is not expected in the environmental pH range of 4 – 9.
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to octanol from water based on predominantly hydrophobic structure.
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment through hydrophobic and electrostatic mechanisms.
Dissociation Constant	Not determined	Contains anionic functionality and is likely to be ionised in the environmental pH range of 4 – 9
Flash Point	> 100 °C*	SDS
Flammability	Not determined	–
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 would imply oxidative properties

* Properties of a product containing the notified polymer at ≤ 70% concentration in a solvent.

DISCUSSION OF PROPERTIES
The notified polymer is imported as a component of a solution from which it will not be isolated.

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the limited physico-chemical data submitted, the notified polymer cannot be 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 (at ≤ 70% concentration) will be initially imported as a component of the product Dispex® Ultra PX 4525, for sale to paint manufacturers. The notified polymer will also be imported in finished paints at concentrations ≤ 1%. No repackaging of the imported paints will occur in Australia. The product Dispex® Ultra PX 4525 will only be used to reformulate industrial and automotive paints.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 30	< 30	< 30	< 30	< 30

PORT OF ENTRY
Major ports of Australia

TRANSPORTATION AND PACKAGING
The notified polymer as a component of the product Dispex® Ultra PX 4525 will be imported in 180 kg closed head steel drums or 20 kg closed head plastic jerricans. It will be transported by road to third party storage facilities. Delivery of the product Dispex® Ultra PX 4525 to end users will occur as required.

The imported and reformulated finished paints containing the notified polymer will be stored and transported in 1 – 10 L lined steel cans and 210 kg lined steel drums.

USE
The notified polymer (at final use concentrations of ≤ 1%) will function as a pigment dispersant in water or solvent based industrial and automotive paints.

OPERATION DESCRIPTION

Reformulation/repackaging
The notified polymer will be imported in solvent at ≤ 70% concentration as a component of a product to be used as a dispersant for a range of inorganic and organic pigments in paints.

At reformulation sites, the reformulation of paints containing the notified polymer will occur in high speed blending tanks using a batch process. The product will be added by gravity feed and low pressure transfer pump to the blending tank that contains a mixture of solvents, water and resins. Dry pigments will then be added, and a combination of high and low speed mixing will be used to blend the paint components under local exhaust ventilation for up to 24 hours. During mixing, the tanks will be in an enclosed environment.

Once the dispersion of the pigment into the liquid component is complete, samples will be taken for quality control (QC) testing. Quality assurance (QA) personnel will take samples and test the final paint formulations containing the notified polymer in a laboratory. Samples will be taken by dipping a container into the mixer and transferring the paint into a clean, sealed 200 mL container.

Filling line staff will operate and clean the automated filling equipment. The finished paint products containing the notified polymer (at ≤ 1% concentration) will be filled into 1 – 10 L cans or 210 kg drums by gravity feed or low pressure pump transfer. Filling lines will be equipped with ventilation extraction systems. The finished paint products will be stored in warehouses and further distributed to customers.

Reformulation equipment used to produce finished paint products containing the notified polymer will be flushed with water for cleaning. The waste liquids will then be either recycled for reuse in the paint manufacturing facility or disposed of in accordance with environmental regulations.

End-use operations
Final paint products containing the notified polymer (at ≤ 1% concentration) will be applied at industrial facilities including automotive repair facilities and protective coatings application facilities. Applications will be done primarily by spray under ventilation in engineered facilities, with limited brush and roller applications. Application equipment used to apply paints containing the notified polymer will be cleaned with water. Waste water from this process will then be disposed of in accordance with environmental regulations.

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	1	4
Process operator	2.5	40
Quality control	0.5	40
Packaging	2	40
End use	1	60

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 products containing the notified polymer will be sealed in containers during transport.

Reformulation
During reformulation operations, dermal and ocular exposure of workers to the notified polymer at ≤ 70% concentration is possible when weighing and transferring of the product from imported containers into blending tanks. The loading operation will be carried out under a fume extractor and blending will occur in a closed mixing tank under local exhaust ventilation. Inhalation of the notified polymer is not expected unless aerosols are generated during the operations. The notifier stated that personal protective equipment (PPE), such as coveralls, gloves, suitable respirators, and eye protection, will be used when carrying out reformulation activities. During filling operations, potential exposure of workers to the notified polymer in finished paint products (at ≤ 1% concentration) will likely be through dermal or ocular routes. The exposure is expected to be minimal due to the use of automated/enclosed systems and appropriate PPE.

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

End use
The paints containing the notified polymer will be used at automotive repair facilities, and protective coatings application facilities. Dermal and ocular exposure of industrial users to the notified polymer at ≤ 1% concentration may occur during application of the finished paints by brush, roller or spray. In addition, dermal and ocular exposure can occur when opening cans of the paints and manually pouring the contents, and during connecting and disconnecting transfer hoses to spray equipment. If leakages happen, industrial users may also be potentially exposed to the notified polymer at ≤ 1% concentration.

Spray applications will be performed within spray booths. Workers may be exposed to the notified polymer at ≤ 1% concentration by inhalation of the aerosolised paint during spray applications. Inhalation is expected to be minimal as the paint is applied in ventilated spray booths and workers are expected to use appropriate personal protective equipment (PPE), including full-face breathing apparatuses, disposable overalls, impervious gloves and safety boots.

Dermal, ocular and inhalation exposure to the notified polymer at ≤ 1% concentration can also occur during the cleaning of the spray equipment. This operation takes place within purpose-built enclosed cabinets and operators are expected to wear appropriate PPE including overalls, glasses or goggles, impervious gloves and respirators during the cleaning procedure.

6.1.2. Public Exposure
The products containing the notified polymer will only be used by industrial users and will not be sold to the public for do-it-yourself (DIY) use.

Once applied, the paint containing the notified polymer will be cured and the notified polymer is expected to be trapped within the inert coating matrix. It is not expected to be available for exposure after curing.

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*
Skin irritation (*in vitro*) Reconstructed Human Epidermis Model (EpiDerm™)	irritating
Eye irritation (*in vitro*) Bovine Corneal Opacity and Permeability (BCOP) Test	severely irritating

Toxicokinetics, metabolism and distribution
The notified polymer is expected to have a low absorption across biological membranes based on its predominant hydrophobic structures and high molecular weight (Mn > 1,000 g/mol) with low levels of low molecular weight species (< 10% molecules having molecular weight < 500 g/mol).

Acute toxicity
No acute toxicity study data was provided for the notified polymer. In the SDS submitted, the notified polymer is classified under GHS as acute toxicity (oral) category 4 with LD50 between 300 and 2,000 mg/kg bw in rats.

Irritation
In a bovine corneal opacity and permeability (BCOP) test, the mean *in vitro* irritancy score (IVIS) was 60.2. Based on OECD TG 437 (OECD, 2017), the notified polymer is predicted to cause serious eye damage warranting Category 1 classification under GHS.

Two *in vitro* assays using EpiDerm™ human skin models were conducted to evaluate skin corrosion and irritation properties of the notified polymer. The skin corrosion test (SCT) and the skin irritation test (SIT) were carried out according to OECD TG 431 and OECD TG 439, respectively. The SCT results indicated that the notified polymer was not corrosive. However, the SIT results showed that the relative mean viability of tissues treated with the notified polymer was < 50%. Based on OECD TG 439 (OECD, 2015), the notified polymer is considered to be a skin irritant warranting Category 2 classification under GHS.

Health hazard classification
Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of 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*
Skin irritation (Category 2)	H315: Causes skin irritation
Serious eye damage (Category 1)	H318: Causes serious eye damage

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The main hazard concerns posed by the notified polymer are skin and eye irritation.

Reformulation
During reformulation operations, workers may be exposed to the notified polymer at ≤ 70% concentration when weighing and transferring of the product from imported containers into blending tanks. Workers may also be exposed to the notified polymer in finished paint products at ≤ 1% concentration during filling operations. The potential exposure routes are expected to be inhalation, dermal and ocular. Systemic absorption of the notified polymer through biological membranes is expected to be limited due to its relatively high molecular weight and predominant hydrophobic structures. The proposed use of engineering controls including automated and enclosed systems will reduce the potential for exposure during reformulation, and hence reduce the risk of possible adverse effects. In addition, the use of appropriate PPE including impervious gloves, safety glasses and protective clothing will further reduce the risk.

End-use
End-users may be exposed to the notified polymer at ≤ 1% concentration when handling products containing the notified polymer and during spray applications at industrial sites. Industrial users may also be potentially exposed to the notified polymer at ≤ 1% concentration if leakages occur. The potential exposure routes are expected to be inhalation, dermal and ocular. Systemic absorption of the notified polymer is expected to be limited due to its relatively high molecular weight and predominant hydrophobic structures. The proposed use of engineering controls including spray booths and use of appropriate PPE including respirators, impervious gloves and safety glasses will reduce the potential for exposure during spray applications, and hence reduce the risk of possible adverse effects.

Provided that the work place 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.

6.3.2. Public Health
Products containing the notified polymer will only be used by workers in areas which will not be accessible to the general public. Members of the public may come into contact with articles coated with paint and coating products containing the notified polymer. However, the notified polymer is expected to be cured into 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 into Australia either in end-use paints, or in the product for reformulation into the end-use paints. The reformulation process will involve adding the product to the paint mixing tank by gravity feed or low pressure pumps, where it will be blended with other ingredients, and then automatically filled into end-use containers. Liquid waste containing the notified polymer from reformulation equipment cleaning will be either reused in the paint manufacturing facility or disposed of in accordance with local government regulations. Release of products containing the notified polymer to the environment in the event of accidental spills or leaks during reformulation, storage and transport is expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations. Empty import containers will be collected by an approved waste contractor for reuse or disposal in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

Final paint products containing the notified polymer will be applied at industrial automotive repair facilities and protective coatings application facilities. Applications will be done primarily by spray under ventilation in engineered facilities, with limited brush and roller applications. The main release of the notified polymer is likely from overspray during use. The overspray is expected to be collected using standard engineering controls such as spray booths before being disposed of to landfill. Wastewater from application equipment cleaning will be disposed of in accordance with local government regulations. During use, the notified polymer may also be released to the environment as accidental spills. These releases are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified polymer is expected to share the fate of the article to which it has been applied; either subjected to metal reclamation or being disposed of to landfill at the end of their useful lives. Residual notified polymer in empty end-use containers is expected to be cured into an inert solid matrix and be disposed of to landfill along with the empty containers.

7.1.2. Environmental Fate

As a result of its use pattern, the majority of the notified polymer is expected to share the fate of the article to which it has been applied; either subjected to metal reclamation or being disposed of to landfill at the end of their useful lives. During metal reclamation, the notified polymer will thermally decompose to form water vapour and oxides of carbon. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile. Thus, release of the notified polymer from the assessed use pattern is not expected to lead to ecotoxicologically significant concentrations in the aquatic environment. Based on its structure, the notified polymer is likely to be biodegradable. The notified polymer is not expected to be bioaccumulative due to its high molecular weight. In landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified polymer to the aquatic environment will be limited based on its reported use pattern.

7.2. Environmental Effects Assessment

No ecotoxicity data for the notified polymer were submitted. Anionic polymers are generally of low toxicity to fish and daphnia, however they are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone, leading to chelation of essential nutrients (Boethling & Nabholz, 1997). However, this does not apply to the notified polymer and it is therefore not considered to be an over-chelation hazard to algae.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has not been calculated as release of the notified polymer to the aquatic environment will be limited based on its reported use pattern.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) for the aquatic compartment has not been calculated as release of the notified polymer to the aquatic environment will be limited based on its reported use pattern.

On the basis of the assumed low hazard and the reported use pattern as a component of industrial and automotive paints, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

B.1. Corrosion/Irritation – skin (*in vitro* EpiDerm™ reconstructed human epidermis model)

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: Undiluted test substance

Remarks - Method: Two *in vitro* assays were part of the corrosion and skin irritation test strategy: the skin corrosion test (SCT) according to OECD TG 431 and skin irritation test (SIT) according to OECD TG 439.

Test substance was used as supplied.

Due to the ability of the test substance to reduce 3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyltetrazolium bromide (MTT) directly, killed control (KC) tissues were applied in parallel.

For the SCT the positive control used was potassium hydroxide (8 N) and the negative control was sterile de-ionised water.

For the SIT the positive control was 5% (w/v) sodium dodecyl sulfate (SDS) in sterile water and the negative control was sterile calcium and magnesium-free Dulbecco's Phosphate Buffered Saline (PBS).

No major deviations were noted from the test guidelines.

RESULTS

SCT – exposure period: 3 minutes

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	2.19	100.00	2.70
Test substance	1.96	88.90	6.90
Positive control	0.26	11.70	0.40

OD = optical density; SD = standard deviation

SCT – exposure period: 1 hour

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	2.15	100.00	4.80
Test substance	1.93	89.00	10.70
Positive control	0.13	6.10	0.00

OD = optical density; SD = standard deviation

SIT

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	2.29	100.00	2.70
Test substance	0.10	4.50	1.50
Positive control	0.08	3.50	0.30

OD = optical density; SD = standard deviation

Remarks - Results: The results of the KC tissues indicated an increased MTT reduction (equivalent to mean viability of 0.7% and 0.5% of negative control for SCT 3 minute and 1 hour exposure, respectively). Thus for the test substance the final mean viability was calculated after KC correction.

The criteria for acceptance of both the negative and positive controls were satisfied, as were the requirements for standard deviation between the replicates.

Skin corrosion test
The relative mean viability of tissues treated with the test substance was 88.9% after an exposure period of 3 minutes and 89.0% after an exposure period of 1 hour, not meeting the criteria for classification as a corrosive under the GHS based on OECD TG 431.

Skin irritation test
As the relative mean viability of tissues treated with the test substance was 4.5%, the test substance met the criteria for classification as a skin irritant Category 2 under GHS according to OECD TG 439.

CONCLUSION The notified polymer was irritating to the skin under the conditions of the test.

TEST FACILITY BASF (2015b)

B.2. Irritation – eye [*in vitro* bovine corneal opacity and permeability (BCOP) test]

TEST SUBSTANCE Notified polymer

METHOD OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage

Vehicle De-ionised water

Remarks - Method The notified polymer was tested as a 10% emulsion in de-ionised water according to the surfactant protocol.

The positive control was ethanol (100% concentration) and the negative control was sterile de-ionised water.

Due to borderline results and not satisfying the acceptance criteria, the BCOP test was repeated.

No other major deviations from the test guidelines.

RESULTS

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	2.55 (± 1.8)	0.00	2.55 (± 1.8)
*Test substance**	17.75 (± 3.2)	2.83 (± 0.5)	60.20 (± 8.7)
*Positive control**	39.50 (± 8.0)	1.06 (± 0.2)	55.45 (±10.5)

SD = Standard deviation; IVIS = *in vitro* irritancy score
*Corrected for background values

Remarks - Results The results reported in the table are the mean value of 2 BCOP tests.

The acceptance criteria for both the negative and positive controls were satisfied.

Of the 6 corneas tested in 2 tests, 2 produced IVIS values below the cut off for serious eye damage (46.5 and 54.9) and the other 4 produced values above this cut off (69.8, 68, 58.5 and 63.5).

The BCOP test predicted the notified polymer to be ocular corrosive or

	severe irritant (IVIS value > 55), warranting Category 1 classification according to GHS.
CONCLUSION	The notified polymer was predicted to cause ocular corrosion or severe eye irritation under the conditions of the test.
TEST FACILITY	BASF (2015a)

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