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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Efka FA 4609

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/2020	BASF Australia Ltd	Polymer in Efka FA 4609	Yes	≤ 60 tonnes per annum	Component of industrial paints and inks

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 Corrosion/Irritation (Category 2)	H315 – Causes skin irritation
Eye Damage/Irritation (Category 1)	H318 – Causes serious eye damage

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.

As the notified polymer will be used on materials with direct food contact, the public report of this assessment will be forwarded to Food Standards Australia New Zealand (FSANZ) for their information.

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 Corrosion/Irritation (Category 2): H315 – Causes skin irritation
  - Eye Damage/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.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer:
  – Enclosed, automated processes, where possible

- Local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid skin and eye contact

- 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
  - Coveralls
  - Eye protection

  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 containment, physical 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 1000 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 inks, 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 Number Average Molecular Weight (NAMW) ≥ 1,000 g/mol

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume, and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China (2014)
Korea (2014)
USA (2015)
Canada (2016)

2. IDENTITY OF CHEMICAL

MARKETING NAME
Efka FA 4609 (product containing the notified polymer at < 60% concentration)

MOLECULAR WEIGHT
NAMW 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: Yellow to red liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Introduced in organic solvent
Boiling Point	Not determined	Introduced in organic solvent
Density	1,020 kg/m^3 at 20 °C	SDS*
Vapour Pressure	Not determined	Based on the high molecular weight of the notified polymer, the vapour pressure is expected to be low
Water Solubility	Not soluble	SDS. Expected to be water dispersible as it is a pigment dispersant in solvent-based paints
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups. However, significant hydrolysis is not expected

		in the environmental pH range of 4 – 9
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer has hydrophobic and hydrophilic functionalities and may partition to the n-octanol/water phase boundary
Adsorption/Desorption	Not determined	The notified polymer is expected to adsorb to soil and sediment through hydrophobic and ion exchange mechanisms
Dissociation Constant	Not determined	The notified polymer contains anionic functionalities and is expected to be ionised in the environmentally relevant pH range of 4 – 9
Flash Point	Not determined	Introduced in flammable organic solvent
Flammability	Not determined	Introduced in flammable organic solvent
Autoignition Temperature	Not self-igniting	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 oxidising properties

* For the notified polymer at < 60% concentration in organic solvent

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

Physical hazard classification
As no physico-chemical data were provided, 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.

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 into Australia at < 60% concentration for reformulation into industrial paints. The notified polymer will also be imported as a component of finished paints and inks at < 10% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 20	< 30	30 - 60	30 - 60	30 - 60

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer will be imported at < 60% concentration in 20 kg plastic jerricans and 200 kg steel drums.

Finished products containing the notified polymer at < 10% concentration will be imported in 1 L, 4 L and 10 L paint cans and 210 kg lined steel drums.

USE
The notified polymer will be used as a component of industrial paints and inks at < 10% concentration. The finished paints will be applied to metal, timber and masonry. The inks will be applied to paper and plastic.

OPERATION DESCRIPTION

Reformulation
The solution containing the notified polymer at < 60% concentration will be transferred to the mixing vessel by gravity feed or low pressure pumps where it will be blended with other ingredients in the presence of local exhaust ventilation. Following blending, samples of the finished products will be taken for quality control testing. The finished paints containing the notified polymer at < 10% concentration will be filled into containers through gravity feed or low pressure pumps.

End Use
Paints containing the notified polymer at < 10% concentration will mainly be applied by spray in purpose-built industrial spray facilities at smash repair shops, and protective paint application facilities. These products may also be applied with brush or roller.

Inks containing the notified polymer at < 10% concentration will be applied to substrates using flexographic or gravure printing.

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
Warehouse	1	4
Process operator	2.5	40
Quality control	0.5	40
Packaging	2	40
End use (painters, printer operators)	1	60

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

Reformulation processes
Dermal and ocular exposure to the notified polymer at < 60% concentration may occur when connecting or disconnecting transfer hoses, cleaning or maintaining equipment and testing for quality control. Inhalation exposure to the notified polymer may also occur if aerosols are formed. Exposure should be minimised through the use of enclosed and automated systems, local exhaust ventilation and personal protective equipment (PPE: goggles, impervious gloves, coveralls and respirators) as stated by the notifier.

End-use
Dermal, ocular and inhalation exposure to the notified polymer at < 10% concentration may occur during application of the finished paints. Paint application will be primarily by spray, but potentially with brush and roller. As stated by the notifier, the potential for exposure should be minimised through the use of PPE (goggles, impervious gloves, coveralls) by workers, including the use of respiratory protection during spray application. Inhalation exposure should be further mitigated through the use of exhaust ventilation and spray booths, where possible. Once the paint is dried, the notified polymer will be bound into an inert solid matrix within the substrate and will not be available for exposure.

Dermal and ocular exposure to the notified polymer at < 10% concentration in inks may occur when manually pouring the ink into the printing apparatus and when cleaning residual ink from printers. Inhalation exposure to the notified polymer is not expected given the presumed low vapour pressure of the polymer (on account of its high molecular weight) and the low likelihood of aerosols being released during printing. In addition, local exhaust ventilation is expected to be employed in areas surrounding the printing machines. After printing, the notified polymer will be cured into the substrate matrix and will not be available for exposure.

6.1.2. Public Exposure
Finished paints and inks containing the notified polymer at < 10% concentration will be for industrial use only and are not expected to be sold to the public. Though public exposure to paints and inks containing the notified polymer at < 10% concentration is likely to occur, the notified polymer will be bound into an inert solid matrix within the substrate once it has dried and will not be available for systemic exposure.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Skin corrosion – *in vitro* (EpiDerm™ model)	non-corrosive
Skin irritation – *in vitro* (EpiDerm™ model)	irritating
Eye irritation – *in vitro* EpiOcular™ Eye Irritation Test	no prediction could be made
Eye irritation – *in vitro* Bovine Corneal Opacity Test (BCOP)	severely irritating

The notified polymer is of high molecular weight (> 1000 g/mol but contains a high percentage (> 20%) of low molecular weight species (< 1000 g/mol), therefore there is potential for the notified polymer to cross biological membranes.

The notified polymer was determined to be irritating but non-corrosive to the skin in *in vitro* studies conducted using reconstructed human epidermis models.

In an *in vitro* EpiOcular™ eye irritation test, no prediction could be made from the test results on the eye irritation potential of the notified polymer. However, in an *in vitro* bovine corneal opacity and permeability (BCOP) test, the notified polymer was determined to be a severe eye irritant.

The notified polymer does not contain structural alerts for skin sensitisation or genotoxicity.

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 Corrosion/Irritation (Category 2)	H315 – Causes skin irritation
Eye Damage/Irritation (Category 1)	H318 – Causes serious eye damage

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer is irritating to the skin and severely irritating to eyes.

Reformulation

During reformulation, workers may be at risk of skin irritation and eye damage when handling the notified polymer as introduced at < 60% concentration and in reformulated products at < 10% concentration. The notifier states that worker exposure will be limited through the use of engineering controls such as enclosed systems, automated processes and local exhaust ventilation. The use of appropriate PPE (coveralls, imperious gloves and eye protection) will also be used to limit worker exposure.

End-Use

Workers may be at risk of skin irritation and eye damage when handling paints and inks containing the notified polymer at < 10% concentration. The notifier states that worker exposure will be limited through the use of engineering controls such as enclosed systems, automated processes and local exhaust ventilation (to remove solvent and any other airborne ink components). The use of appropriate PPE (coveralls, imperious gloves and eye protection) will also be used to limit worker exposure.

Exposure is not anticipated for workers who might make dermal contact with the notified polymer when handling dried end products, as the notified polymer will be incorporated into the polymer matrix and will not be available for exposure.

Therefore, under the occupational settings described, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer is intended for use in industrial applications only. The public may come into dermal contact with substrates on which the paint or ink is applied. However, once the paint or ink is dried, the notified polymer will be incorporated into the polymer matrix and will not be available for exposure.

As some uses of ink containing the notified polymer will be for the exterior of food packaging, it is possible that indirect food contact may occur. It is anticipated that the notified polymer is not expected to migrate from the dried ink as it will be fully reacted into an inert matrix. The manufacturer of the food packaging is responsible for ensuring the ink containing the notified polymer is inert so that the levels of reactive, low molecular weight species are below the limits of detection. Therefore provided end-users (i.e. food packaging manufacturers) employ good manufacturing processes to ensure complete curing of the ink the risk to public health is not considered to be unreasonable.

The public report of this assessment will be forwarded to Food Standards Australia and New Zealand (FSANZ) for their information.

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 as a component of a pigment dispersant, and hence will not be manufactured in Australia. The dispersant containing the notified polymer will be mixed with solvents and resins at sites in Australia to form paints or inks. There may be release of the notified polymer when formulating paints or inks, but this release will be insignificant because it is anticipated that cleaning wastes from reformulation equipment will be recycled for reuse in the paint or ink manufacturing facility or disposed of via accredited waste contractors. Wastes and spills (estimated at 1% of annual import volume) during reformulation will be disposed of to landfill.

Leaks and spills of dispersant or paints containing the notified polymer during storage and transportation are also likely to be minimal as they are expected to be contained, absorbed onto inert material and disposed of to landfill. Empty containers with residual dispersant containing the notified polymer will be disposed of as trade waste in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

Release to the environment via sewers during paint application is unlikely due to management controls, closed systems and no expected do-it-yourself (DIY) use by members of the public. It is expected that ink containing the notified polymer will be used on paper or cardboard substrates. Once applied, the paint or ink will be cured and the notified polymer will be bound within the matrix. Wastes from overspray, application equipment washings and residues in empty containers (the notifier estimates ~ 30%, 5% and 2.5% of annual import volume, respectively) are expected to go to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to share the fate of the product to which it has been applied and be disposed of to landfill or recycled at the end of its useful life. However, as the notified polymer is also to be used in inks, there is a potential for release to the aqueous environment from paper/cardboard recycling via sewage treatment plants (STPs).

7.1.2. Environmental Fate

No environmental fate studies were submitted for the notified polymer. The notified polymer contains anionic functionalities. It is expected to be ionised in the environmentally relevant pH range of 4 – 9. The notified polymer contains hydrolysable functional groups. However, significant hydrolysis is not expected in the environmental pH range of 4 – 9. The notified polymer is expected to adsorb to soil and sediment based on its high molecular weight and anionic functionality. The notified polymer has a high molecular weight and it is not expected to be bioavailable. It will eventually degrade via biotic or abiotic processes to form oxides of carbon and phosphorus.

Apart from recycling of ink-applied paper-based products, the notified polymer should be irreversibly bound into the inert paint matrix during its use. The notified polymer will share the same fate as the substrates to which it has been applied and will eventually be disposed of to landfill or will enter metal recycling. In this form, it is not expected to be bioavailable, biodegradable or mobile. It will eventually degrade in landfill via biotic or abiotic processes or be thermally degraded during metal recycling to form oxides of carbon and phosphorus.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer will be used in paints and inks. No estimation of the proportion of notified polymer for the two uses has been made. In a worst-case it is assumed that 100% of the notified polymer is used for inks. The current Australian Waste Report records 60% of paper and cardboard in Australia are recycled (Pickin and Randell, 2017). During the recycling, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks from the fibres. Aqueous wastes are expected to be sent to the sewage treatment plant (STP) for processing. Under a worst-case scenario assuming 0% of the notified polymer is removed via absorption to sludge in the sewage treatment plant, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 28 µg/L [PECriver = 138 kg notified polymer/day ÷ (200 L/person/day × 24.4 million people) × 1 (dilution factor)].

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The notified polymer is expected to be dissociated in the aquatic environment under environmental conditions. The dissociated anionic polymer is expected to be practically non-toxic to fish and invertebrates (US EPA 2016). Anionic polymers are known to be moderately toxic to algae when there are carboxylic acid groups on alternating carbons of the polymer backbone, however, this does not apply to the notified polymer (Boethling & Nabholz, 1997).

7.3. Environmental Risk Assessment

The notified polymer is expected to be of low hazard and a PNEC has not been determined. Therefore, the risk quotient (Q = PEC/PNEC) for the notified polymer cannot be calculated. A worst-case scenario PEC of 28 µg/L has been calculated from release of the notified polymer from printed paper or cardboard during recycling, but this is unlikely to be eco-toxicologically significant based on the low hazard of the notified polymer. The actual PEC is expected to be much lower as use of the notified polymer in metal paints are not expected to lead to exposure to the aquatic environment. Therefore, based on the low hazard to aquatic organisms and its use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

B.1. Corrosion – skin (*in vitro* Reconstructed Human Epidermis Test)

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 431 *In vitro* Skin Corrosion - Human Skin Model Test (2013)
EpiDerm™ Reconstructed Human Epidermis Model

Vehicle: None

Remarks - Method: No significant protocol deviations.

The test substance (~110 mg) was applied to the tissues in duplicate. Following exposure periods of 3 minutes (room temperature; test 1) and 1 hour (37 °C; test 2), the tissues were washed with PBS, carefully wiped with a MEROCEL® sponge (to remove residual test substance), and then incubated with MTT [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolim bromide; 1.0 mg/mL] at 37 °C for 3 hours to test cell viability. After extraction, optical densities were determined at 570 nm.

The study authors noted that preliminary tests had been conducted, which indicated that the test substance does not directly interfere with MTT.

Positive and negative controls were run in parallel with the test substance:
- Negative control (NC): water
- Positive control (PC): potassium hydroxide (8M)

RESULTS

Test material	*Test 1 (3 minute exposure period)*		*Test 2 (1 hour exposure period)*	
	Mean OD_{570} of duplicate tissues	*Relative mean viability (%)*	*Mean OD_{570} of duplicate tissues*	*Relative mean viability (%)*
Negative control	2.013	100	1.709	100
Test substance	1.417	70	1.278	75
Positive control	0.327	16	0.137	8

OD = optical density

Remarks - Results: The variability between tissues treated with the test substance was slightly above the acceptable range during the 1 hour exposure period. The study authors suggest that this is not expected to affect the integrity or validity of the study because the relative viabilities of each tissue treated for 1 hour led to the same prediction for corrosion. Also, the negative and positive controls performed as expected, confirming the validity of the test system.

The mean tissue viability of tissues treated with the test substance was ≥ 50% for 3 minutes exposure and ≥ 15% for 1 hour exposure compared to the negative control, indicating that the test substance is non-corrosive to the skin under the conditions of the test.

The positive and negative controls satisfied the acceptance criteria of the study, confirming the validity of the test system.

CONCLUSION: The notified polymer is non-corrosive to the skin under the conditions of the test.

TEST FACILITY: BASF (2014a)

B.2. Irritation – skin (*in vitro* Reconstructed Human Epidermis Test)

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method (2013) EpiDerm™ Reconstructed Human Epidermis Model
Vehicle	None
Remarks - Method	No significant protocol deviations.

The test substance (~110 mg) was applied to the tissues in triplicate. Following an exposure period of 25 minutes at room temperature and then 35 minutes at 37 °C, the tissues were washed in PBS, carefully wiped with a MEROCEL® sponge (to remove residual test substance), and then incubated in fresh medium at 37 °C for ~24 hours. The tissues were then transferred again to fresh medium and incubated at 37 °C for ~18 hours. The tissues were then treated with MTT and incubated at 37 °C for 3 hours to test cell viability. After extraction, optical densities were determined at 570 nm.

The study authors noted that preliminary tests had been conducted, which indicated that the test substance does not directly interfere with MTT.

Positive and negative controls were run in parallel with the test substance:
- Negative control (NC): PBS
- Positive control (PC): sodium dodecyl sulphate (5%)

RESULTS

Test 1

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	1.948	100	3
Test substance	1.026	53	22
Positive control	0.052	3	0

OD = optical density; SD = standard deviation

Test 2

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	2.231	100	4
Test substance	1.062	48	35
Positive control	0.072	3	0

OD = optical density; SD = standard deviation

Test 3

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	2.102	100	4
Test substance	0.219	10	8
Positive control	0.052	2	0

OD = optical density; SD = standard deviation

Remarks - Results

The study authors note that the SD of relative mean viability of the test substance in Test 1 was out of the acceptance range (i.e. ≤ 20%) and that the percentage viabilities of individual tissues (not shown) treated by the test substance did not indicate a clear prediction of viability. As such, the study authors performed a second irritation test.

The same occurrence was noted by the study authors following Test 2.

As such, the study authors performed a third irritation test. The results of the third irritation test were within the acceptance range. As the mean tissue viability of tissues treated with the test substance was < 50%, the test substance was predicted to be an irritant, requiring a GHS hazard classification of Category 2 for skin irritation

The positive and negative controls satisfied the acceptance criteria of the study, confirming the validity of the test system.

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

TEST FACILITY BASF (2014a)

B.3. Irritation – eye (*in vitro* EpiOcular™ Eye Irritation Test)

TEST SUBSTANCE Notified polymer

METHOD Similar to OECD TG 492 Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage

Vehicle None

Remarks - Method No significant protocol deviations were noted by the study authors.

Positive and negative controls were run in parallel with the test substance:
- Negative control (NC): de-ionised water
- Positive control (PC): methyl acetate

RESULTS

Test material	*Mean OD_{570} of duplicate tissues*	*Relative mean viability (%)*
Negative control	1.531	100
Test substance	0.262	17
Positive control	0.478	31

OD = optical density

Remarks - Results The variability between tissues treated with the test substance was slightly above the acceptable range. The study authors suggest that this is not expected to affect the integrity or validity of the study because the negative and positive controls performed as expected, and the relative mean viabilities of each tissue treated with the test substance lead to the same prediction for irritation.

Each tissue treated with the test substance displayed a tissue viability of < 60%, indicating no prediction can be made and further testing with other test methods are required.

CONCLUSION No prediction could be made for the notified polymer under the conditions of the test.

TEST FACILITY BASF (2014b)

B.4. Irritation – eye (*in vitro* Bovine Corneal Opacity and Permeability 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 (2013)
Vehicle	None
Remarks - Method	No significant protocol deviations were noted by the study authors. Positive and negative controls were run in parallel with the test substance: - Negative control (NC): de-ionised water - Positive control (PC): dimethylformamide

RESULTS

BCOP Test

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Negative control	3.3 (± 4.0)	0.005 (± 0.003)	3.3 (± 4.0)
*Test substance**	78.6 (± 13.2)	0.002 (± 0.001)	78.7 (± 13.2)
*Positive control**	81.8 (± 1.9)	0.226 (± 0.045)	85.2 (± 1.5)

IVIS = *in vitro* irritancy score
*Corrected for background values

Remarks - Results	The positive control was marginally below the historical range and therefore did not meet the acceptance criteria for the test. The study authors suggest that this is not expected to affect the integrity or validity of the study because the negative control and test substance did meet the acceptance criteria. The IVIS for the test substance was > 55 indicating the test substance to be a severe irritant, requiring a GHS hazard classification of Category 1 for eye damage.
CONCLUSION	The notified polymer is severely irritating to the eye under the conditions of the test.
TEST FACILITY	BASF (2014b)

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