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

PUBLIC REPORT

Dehypon E 126 / E 127

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/1930 | BASF Australia Ltd | Dehypon E 126 / E 127 | ND* | ≤ 100 tonnes per annum | Component of rinse aids for automatic dishwashers |

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

| <i>Hazard classification</i> | <i>Hazard statement</i> |
|------------------------------|--|
| Acute Category 2 | H401 – Toxic to aquatic life |
| Chronic Category 3 | H412 – Harmful to aquatic life with long lasting effects |

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 and the reported use pattern, 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:
 - Enclosed and automated system
 - Adequate general ventilation and local exhaust ventilation if necessary
- 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 contact with skin and eyes
- 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:
 - Gloves

- Goggles or face shields
- Coveralls

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

- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System 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 1000 Da;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from component of rinse aids for automatic dishwashers, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

(Material) Safety Data Sheet

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ Da.

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, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Melting point/Boiling point, Specific Gravity/Density, Partition Co-efficient, Dissociation Constant, Particle Size, Flash Point

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

US (2009) Canada (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Dehypon E 126
Dehypon E 127

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 95%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

No losses by volatilisation, exudation or leaching are expected from the notified polymer.

DEGRADATION PRODUCTS

No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use. Thermal decomposition may release toxic fumes containing products of combustion such as carbon dioxide and carbon monoxide.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: greyish paste

| Property | | Value | Data Source/Justification |
|-----------------|----------------------|-----------------------------|----------------------------------|
| Melting Point | Point/Freezing Point | 32-34 °C | (M)SDS |
| Boiling Point | | > 250 °C (pressure unknown) | (M)SDS |

| | | |
|---|---|--|
| Density | Approx. 1,022 kg/m ³ at 40 °C | (M)SDS |
| Vapour Pressure | < 1 × 10 ⁻⁷ kPa at 20 °C | Measured |
| Water Solubility | Partially extractable in deionised water and in buffers at pH 2, 7 and 9. | Measured. Saturation concentration was not achieved, indicating that solubility is due to soluble components of the polymer. |
| Hydrolysis as a Function of pH | t _{1/2} > 1 year at pH 4, 7 and 9 | Measured |
| Partition Coefficient (n-octanol/water) | Not determined | Expected to partition to phase boundaries based on surface activity |
| Adsorption/Desorption | Log K _{OC} ≥ 3.65 at 23 °C | Measured; expected to adsorb to soil and sediment based on surface activity |
| Dissociation Constant | Not determined | Contains no dissociable functionalities |
| Particle Size | Not determined | Paste |
| Flash Point | Approx. 265 °C (pressure unknown) | (M)SDS |
| Solid Flammability | Not highly flammable | Measured |
| Autoignition Temperature | 386 °C | Measured |
| Explosive Properties | Not explosive | Contains no explosives that would imply explosive properties. |
| Oxidising Properties | Not oxidising | Contains no functional groups that imply oxidative properties. |

DISCUSSION OF PROPERTIES

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

Reactivity

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

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 chemical will be imported into Australia at 100% concentration or as a component of formulated products (at < 10% concentration).

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

| Year | 1 | 2 | 3 | 4 | 5 |
|--------|-------|-------|--------|--------|--------|
| Tonnes | 30-60 | 30-60 | 50-100 | 50-100 | 50-100 |

PORT OF ENTRY

Melbourne, Sydney, Brisbane

IDENTITY OF RECIPIENTS

BASF Australia Ltd

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in the imported containers such as 25 kg open head plastic drums or 1,000 L intermediate bulk containers (IBC) and transported by road to the warehouse, and later to reformulation sites.

Formulated products containing the notified polymer will be imported in pack sizes < 1 L by sea in a shipping container and transported by road to distribution warehouses around the country. The products will then be distributed by road around Australia to supermarkets and related retail outlets.

USE

Low foaming wetting agent for use in rinse aids for automatic dishwashing detergents at < 10%

OPERATION DESCRIPTION

At the formulation sites, the imported notified polymer (up to 100%) will be added to 150 – 200,000 L stainless steel mixing vessels, either directly from a 25 kg drum or via pumping using a metering system from the IBC and then mixed with other ingredients.

The resultant rinse aid product containing < 10% notified polymer will be packed off by gravity feed or pneumatic filling into plastic containers < 1 L for sale through retail outlets.

Professional kitchen workers and the public will use the end use products in automatic dishwashers.

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 | 4 | 50 |
| Warehouse | 2 | 100 |
| Reformulation process operator | 2-3 | 50 |
| Quality control | 1 | 50 |
| Packaging | 3 | 50 |
| End use | 2-0.5 | 365 |

EXPOSURE DETAILS

Transport, storage and warehouse workers

Worker exposure to the notified polymer during the transport and storage of the notified polymer and products containing it not expected, except in the event of an accident where packaging may be breached.

Reformulation process operators may be exposed to the product containing up to 100% notified polymer. Exposure (dermal, inhalation or ocular) is most likely to occur when adding the notified polymer to mixing vessels. The notifier states that exposure is limited by exhaust ventilation and personal protective equipment (PPE), including overalls, gloves, safety goggles and boots. Exposure during quality control is possible, but will be limited by use of PPE.

Packaging workers may be exposed to products containing < 10% notified polymer. Exposure will also be limited by exhaust ventilation and PPE, including overalls, gloves, safety goggles and boots.

End users such as professional kitchen workers may have incidental dermal or ocular exposure to products containing < 10% notified polymer through splashes or contamination of the outside of the packaging.

6.1.2. Public Exposure

There will be potential exposure of the public to the notified polymer (at < 10% concentration) through the use of automatic dishwashing detergents. The principal route of exposure will be dermal, occurring during accidental contact with rinse aid products during filling of reservoirs. Inhalation exposure is not expected, as the vapour pressure of the notified polymer is low.

Rinse aids are used at the end of the washing cycle, and may therefore be deposited at low levels on washed dishes, cutlery and glassware, with the potential for later ingestion. The levels of deposition are expected to be very low, and have been estimated by the notifier at < 1 mg/article, based on information on similar chemicals.

As the products will be used in domestic settings, accidental ingestion by children of the finished rinse aid products may also be possible.

6.2. Human Health Effects Assessment

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

| Endpoint | Test substance | Result and Assessment Conclusion |
|---|--------------------|--|
| Rat, acute oral toxicity | Analogue polymer 1 | LD50 > 2,000 mg/kg bw; low toxicity |
| Rabbit, skin irritation | Analogue polymer 1 | slightly irritating |
| Rabbit, eye irritation | Analogue polymer 1 | slightly irritating |
| Human, skin sensitisation – RIPT (30%) | Analogue polymer 2 | no evidence of sensitisation or irritation |
| Mutagenicity – bacterial reverse mutation | Analogue polymer 1 | non mutagenic |

Since the two analogue polymers contain similar functional groups as the notified polymer and have similar average molecular weight and similar percentage of low molecular weight species, the analogue polymers are considered suitable to estimate the toxicological profile of the notified polymer.

Toxicokinetics, metabolism and distribution

Data is not available on the toxicokinetic properties of the notified polymer. The notified polymer has a high molecular weight > 1,000 Da, a low percentage of low molecular species < 1,000 Da, and a low vapour pressure ($< 1 \times 10^{-7}$ kPa). These indicate a low potential for absorption following ingestion, dermal exposure or inhalation.

Acute toxicity

The notified polymer is expected to have low acute toxicity by the oral route, based on a study in rats on an analogue.

Irritation and sensitisation

Based on a study in rabbits carried out on an analogue, the notified polymer is expected to be slightly irritating to the skin. Skin irritation was not seen in a human repeat insult patch test in humans (RIPT), using 30% of an analogue polymer.

In an eye irritation study in rabbits on an analogue, significant irritation occurred. The effects were mainly conjunctival and had resolved by 7 days. The effects were not classifiable under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). They met the criteria for Eye irritation (Category 2B) under the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*; however this category is not adopted for use in Australia.

An analogue polymer at 30% was not a skin sensitizer in a human repeated insult patch test with challenge (HRIPT).

Mutagenicity/Genotoxicity

An analogue of the notified polymer was not mutagenic in a bacterial reverse mutation assay.

Health hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Limited toxicological data is available for the notified polymer. It is expected to be slightly irritating to the skin and have eye irritation potential. Workers may have dermal and ocular exposure to the notified polymer at up to 100% concentration during reformulation processes. Exposure should be minimised through the stated use of enclosed, automated processes, local exhaust ventilation and PPE. Other workers, such as commercial kitchen

workers, may have incidental exposure to products containing the notified polymer at < 10%, while adding products to automatic dishwasher dispensers. These workers may use PPE to lower exposure.

Overall, the risk to workers from exposure to the notified polymer is not considered to be unreasonable, given the expected use of engineering controls and PPE during reformulation and the limited opportunities for exposure during end-use.

6.3.2. Public Health

Based on available information, the notified polymer is expected to be slightly irritating to skin and have some eye irritation effects. These effects are expected to be reduced at the concentration of use (up to 10%). Based on an analogue study, the polymer is expected to have low acute oral toxicity ($LD_{50} > 2000$ mg/kg).

The public may have incidental dermal or ocular exposure to rinse aids containing the notified polymer at < 10% concentration, during refilling of dispensers in automatic dishwashing machines. The risk of eye irritant effects is present but would be reduced by the expected limited exposure. While the public may potentially ingest very low levels of residues of the notified polymer deposited on dishware, exposure through this route is expected to be further reduced by low bioavailability.

Potential adverse effects from accidental ingestion by children of the finished rinse aid products would be reduced, because of the expected low acute oral toxicity of the notified polymer and its relatively low concentration in products.

Overall, the risk to public health associated with the proposed use of the notified polymer in rinse aids for automatic dishwashing detergents is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as a component of a product for reformulation into finished automatic dishwashing detergents. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the products containing the notified polymer are expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified polymer from this process to the environment is not expected. The process will be followed by automated filling of the formulated products into end-use containers of various sizes suitable for retail. Wastes containing the notified polymer generated during reformulation include equipment wash water, residues in import containers, and spilt materials. It is estimated by the notifier that up to 1% of the import volume of the notified polymer (or up to 1,000 kg) may remain as residues in empty import containers. These will be collected and released to sewers in a worst case scenario, or disposed of to landfill in accordance with local government regulations. Empty import containers are expected to be recycled or disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer is expected to be released to sewer across Australia as a result of its use in automatic dishwashing detergents. A small proportion of the notified polymer is expected to be disposed of to landfill as residue in empty end-use containers.

RELEASE OF CHEMICAL FROM DISPOSAL

It is estimated by the notifier that a maximum of 1% of the import volume of the notified polymer (or up to 1,000 kg), may remain in end-use containers once the dishwashing detergents are used up. Wastes and residue of the notified polymer in empty containers are likely to either share the fate of the container and be disposed of to landfill, or be released to the sewer system when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

Following its use in automatic dishwashing detergents in Australia, the majority of the notified polymer is expected to enter the sewer system, before potential release to surface waters nationwide. Based on the results of a ready biodegradability study, the notified polymer is considered readily biodegradable (78% in 28 days). The notified polymer is also considered to be ultimately and anaerobically biodegradable, based on the results of an anaerobic biodegradation test (91.95% in 60 days). For details of the environmental fate studies, please refer to Appendix C. Based on its surfactant properties, release to surface waters is unlikely to occur as partitioning to sludge and sediment is expected under environmental pH. The notified polymer is not expected to be bioaccumulative, due to its surfactant properties, high molecular weight and ready biodegradability. Therefore, in surface waters the notified polymer is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon.

The majority of the notified polymer will be released to sewer after use. A small proportion of the notified polymer may be applied to land when effluent is used for irrigation, or when sewage sludge is used for soil remediation. The notified polymer may also be applied to land when disposed of to landfill as collected spills and empty container residue. Residues of the notified polymer in landfill, soil and sludge are expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

Based on the reported use in automatic dishwashing detergents, it is assumed that 100% of the total import volume of the notified polymer will be released to the sewer. The release is assumed to be nationwide over 365 days per year. The PEC has been calculated assuming 78% removal of the notified polymer from influent during sewage treatment plants (STPs) processes through biodegradation, based on the most conservative ready biodegradability value of the notified polymer (78% in 28 days).

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment | | |
|---|---------|--------------|
| Total Annual Import/Manufactured Volume | 100,000 | kg/year |
| Proportion expected to be released to sewer | 100% | |
| Annual quantity of chemical released to sewer | 100,000 | kg/year |
| Days per year where release occurs | 365 | days/year |
| Daily chemical release: | 273.97 | kg/day |
| Water use | 200.0 | L/person/day |
| Population of Australia (Millions) | 22.613 | million |
| Removal within STP | 78% | mitigation |
| Daily effluent production: | 4,523 | ML |
| Dilution Factor - River | 1.0 | |
| Dilution Factor - Ocean | 10.0 | |
| PEC - River: | 13.33 | µg/L |
| PEC - Ocean: | 1.33 | 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 (density 1,500 kg/m³). Using these assumptions, irrigation with a concentration of 13.33 µg/L may potentially result in a soil concentration of approximately 88.85 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 444.2 µg/kg and 888.57 µg/kg, respectively.

7.2. Environmental Effects Assessment

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

| Endpoint | | Result | Assessment Conclusion |
|------------------|-----------------------|--|--------------------------------|
| Daphnia Toxicity | 48 h EC50 = 4.7 mg/L | Potentially harmful to aquatic invertebrates with long lasting effects | Toxic to aquatic invertebrates |
| | 21 d NOEC ≥ 0.32 mg/L | | |
| Algal Toxicity | 72 h EC50 = 71 mg/L | Not harmful to algae with long lasting effects | Harmful to algae |
| | 72 h NOEC = 4.3 mg/L | | |

Based on the above acute ecotoxicological endpoints for the notified polymer, it is expected to be toxic to aquatic invertebrates, and is expected to be harmful to algae. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is formally classified as 'Acute Category 2; Toxic to aquatic life'. Based on the chronic toxicity and ready biodegradability of the notified polymer, it is formally classified as 'Chronic Category 3; Harmful to aquatic life with long lasting effects' under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for aquatic invertebrates. A safety factor of 100 was used, given acute endpoints for two trophic levels and two chronic endpoints are available.

| Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment | | | |
|--|------|------|--|
| EC50 (<i>Daphnia</i> , 48 h) | 4.7 | mg/L | |
| Assessment Factor | 100 | | |
| Mitigation Factor | 1.00 | | |
| PNEC: | 47.0 | µg/L | |

7.3. Environmental Risk Assessment

The Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) has been calculated based on the predicted PEC and PNEC.

| Risk Assessment | PEC µg/L | PNEC µg/L | Q |
|-----------------|----------|-----------|-------|
| Q – River | 13.33 | 47 | 0.284 |
| Q – Ocean | 1.33 | 47 | 0.028 |

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified polymer is considered readily biodegradable, and is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in automatic dishwashing detergents, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Vapour Pressure $< 1 \times 10^{-7}$ kPa at 20, 25 or 50 °C

Method OECD TG 104 Vapour Pressure.
 Remarks The method used was stated to be the effusion method, weight loss. At the temperatures used for vapour pressure measurements, the test substance was liquid. Vapour pressure was calculated using a theoretical molar mass for the polymer. Only limited details of the study were provided.
 Test Facility BASF (2015)

Water Solubility 4.601 g/L extractability at 10 g/L concentration in deionised water at 20 °C
 0.484 g/L extractability at 1 g/L concentration in deionised water at 20 °C
 4.416 g/L extractability at 10 g/L concentration in pH 2 buffer at 20°C
 0.447 g/L extractability at 1 g/L concentration in pH 2 buffer at 20°C
 1.453 g/L extractability at 10 g/L concentration in pH 7 buffer at 37 °C
 0.144 g/L extractability at 1 g/L concentration in pH 7 buffer at 37 °C
 4.294 g/L extractability at 10 g/L concentration in pH 9 buffer at 20°C
 0.476 g/L extractability at 1 g/L concentration in pH 9 buffer at 20°C

Method OECD TG 120 Water Extractability of Polymers
 Remarks Samples of the test substance at 10 g/L and 1 g/L concentrations were prepared in deionised water and buffers at pH 2 and 9. Solutions were stirred at 20 °C for 24 hours, then the Total Organic Carbon content analysed. Solutions of the test substance at 10 g/L and 1 g/L concentrations were also prepared in a buffer at pH 7, which were stirred at 37 °C for 24 hours.
 No saturation concentration of the test item was achieved, indicating that the solubility is due to certain soluble fractions of the test item.
 Test Facility Henkel (2014a)

Hydrolysis as a Function of pH $t_{1/2} > 1$ year at pH 4, 7 and 9

Method OECD TG 111 Hydrolysis as a Function of pH.

| <i>pH</i> | <i>T</i> (°C) | <i>t</i> _{1/2} |
|-----------|---------------|-------------------------|
| 4 | 25 | > 1 year |
| 7 | 25 | > 1 year |
| 9 | 25 | > 1 year |

Remarks After 5 days under the accelerated conditions of 50 °C the rate of hydrolysis of the test substance was less than 10% at pH 4, 7 and 9. This equates to a half-life at 25 °C of $t_{1/2} > 1$ year. Therefore, it can be concluded that under the conditions of the test, the test substance is expected to be hydrolytically stable.
 Test Facility Henkel (2014b)

Adsorption/Desorption $\log K_{OC} \geq 3.65$ at 23 °C

Method OECD TG 121 Estimation of the Adsorption Coefficient (K_{OC}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)
 Remarks HPLC Method
 Test Facility BASF (2015b)

Solid Flammability Not highly flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids).
 Remarks As brief burning followed by rapid extinction was noted, the preliminary screening test was negative and therefore the substance was not considered highly flammable.
 Test Facility BASF (2012)

Autoignition Temperature 386°C

Method DIN EN 14522
Test Facility BASF (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

| | |
|------------------|--|
| TEST SUBSTANCE | Analogue polymer 1 |
| METHOD | OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method (1996). |
| Species/Strain | Rat/HanIbm:WIST(SPF) |
| Vehicle | Bi-distilled water |
| Remarks - Method | No protocol deviations |

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 |
| 2 | 3 M | 2,000 | 0 |

| | |
|-------------------|--|
| LD50 | > 2,000 mg/kg bw |
| Signs of Toxicity | In two females and two males, ruffled fur was observed on day 1. In one female, hunched posture was noted after 3 hours. No clinical signs were noted after day 2 until the end of observation period. |
| Effects in Organs | No macroscopic findings were noted at necropsy. |
| Remarks - Results | The body weight was within the expected range. |

| | |
|------------|---|
| CONCLUSION | The test substance is of low toxicity via the oral route. |
|------------|---|

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|---------------|----------------|
| TEST FACILITY | RCC Ltd (2000) |
|---------------|----------------|

B.2. Irritation – skin

| | |
|--------------------|---|
| TEST SUBSTANCE | Analogue polymer 1 |
| METHOD | OECD TG 404 Acute Dermal Irritation/Corrosion (1992). |
| Species/Strain | Rabbit/SPF albino |
| Number of Animals | 3 |
| Vehicle | None |
| Observation Period | 14 days |
| Type of Dressing | Semi-occlusive. |
| Remarks - Method | No protocol deviations. Two skin sites on the back were tested with the test substance. |

RESULTS

| <i>Lesion</i> | <i>Mean Score* Animal No.</i> | | | <i>Maximum Value</i> | <i>Maximum Duration of Any Effect</i> | <i>Maximum Value at End of Observation Period</i> |
|------------------------|-----------------------------------|---|---|----------------------|---------------------------------------|---|
| | 1 | 2 | 3 | | | |
| <i>Erythema/Eschar</i> | 1 | 1 | 1 | 1 | < 7 d | 0 |
| <i>Oedema</i> | 0 | 0 | 0 | 0 | - | 0 |

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

| | |
|-------------------|--|
| Remarks - Results | A very slight erythema was observed on all animals on both test fields 1, 24, 48 and 72 hours after termination of exposure. |
|-------------------|--|

On day 7 after exposure small white scales were observed on all animals on both whole test areas. On day 14, there were no signs of skin irritation.

| | |
|------------|--|
| CONCLUSION | The test substance is slightly irritating to the skin. |
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TEST FACILITY Frey-Tox (1999)

B.3. Irritation – eye

TEST SUBSTANCE Analogue polymer 1

METHOD OECD TG 405 Acute Eye Irritation/Corrosion (1987).
 Species/Strain Rabbit/SPF albino
 Number of Animals 3 F
 Observation Period 7 days
 Remarks - Method No protocol deviations. Fluorescein was added to the eyes prior to the 24 h observation.

RESULTS

| <i>Lesion</i> | <i>Mean Score*</i> <i>Animal No.</i> | | | <i>Maximum Value</i> | <i>Maximum Duration of Any Effect</i> | <i>Maximum Value at End of Observation Period</i> |
|-------------------------------|---|-----|-----|----------------------|---------------------------------------|---|
| | 1 | 2 | 3 | | | |
| <i>Conjunctiva: redness</i> | 2.3 | 2.7 | 2 | 3 | < 7 d | 0 |
| <i>Conjunctiva: chemosis</i> | 1.3 | 1.7 | 1 | 2 | < 7 d | 0 |
| <i>Conjunctiva: discharge</i> | 0.7 | 0 | 0 | 2 | < 48 h | 0 |
| <i>Corneal opacity</i> | 0 | 0.7 | 0.3 | 1 | < 72 h | 0 |
| <i>Iridial inflammation</i> | 0 | 0 | 0 | 0 | - | 0 |

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

Remarks - Results One hour post exposure, significant conjunctival effects were evident in all animals. Redness and chemosis were still evident in all animals up to and including the 72 h observation. Discharge was resolved in two animals by the 24 h observation and in one animal by the 48 h observation.

No iridial effects were seen at any of the observations.

Scattered or diffuse opacity over one quarter or less of the cornea was seen in only two of the three animals. The study report suggests that these effects were only noted post-fluorescein administration, and were not evident in the absence of fluorescein. All corneal effects had resolved by the 72 h observation.

On day 7 post application all animals were free of any signs of eye irritation.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY Frey-Tox (2000)

B.4. Skin sensitisation – human volunteers

TEST SUBSTANCE Analogue polymer 2 at 30%

METHOD Repeated insult patch test with challenge – In House Method
 Study Design Induction Procedure: patches were applied 3 times per week, for 9 applications. Following supervised removal and scoring of the first induction patch, participants were instructed to remove all subsequent induction patches at home, 24 hours after application. The evaluation of the site was made again just prior to re-application. If a participant was unable to report for an assigned test day, one makeup day was permitted. This way was added to the induction period.
 If any test site showed a level 2 reaction during the induction phase, application was moved to an adjacent area. Applications were

discontinued if a level 2 reaction was still noted on this new test site. Application would be discontinued if level 3 or level 4 effect was noted. Rest periods consisted of 24 hours following each removal on Tuesday and Thursday and 48 hour following removal on Saturday.

Rest Period: 14 days

Challenge Procedure: a challenge patch was applied to a virgin test site next to the original induction site, following the same procedure for induction. The patch was removed and the site scored at the clinic 24 and 72 hours post-application.

Study Group
Vehicle
Remarks - Method

84 F, 32 M; age range 16-78 years
Distilled water
Occluded. The test substance as a 30% dilution was spread on a 1.9 cm × 1.9 cm patch.

Ninety-nine of the one hundred and sixteen original subjects completed this study, including three discontinuations during the challenge period. The study authors stated that none of the discontinuations were related to the application of the test substance.

RESULTS

Remarks - Results

No results indicative of irritation or sensitisation were noted. One subject had barely perceptible or spotty erythema at the first two observations, but none for the remainder of the study.

CONCLUSION

The test substance was non-sensitising and non-irritating under the conditions of the test.

TEST FACILITY

Consumer Product Testing Co. (2002)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE

Analogue polymer 1

METHOD

OECD TG 471 Bacterial Reverse Mutation Test (1997).

Test 1: Plate incorporation procedure

Test 2: Pre incubation procedure

Species/Strain

S. typhimurium: TA1535, TA1537, TA98, TA100, TA102

Metabolic Activation System

Phenobarbital and β-Naphthoflavone induced rat liver S-9 mix.

Concentration Range in Main Test

Test 1 (with and without metabolic activation): 0, 33, 100, 333, 1,000, 2,500 and 5,000 µg/plate

Test 2 (without metabolic activation): 0, 33, 100, 333, 666, 1,000 and 2,500 µg/plate

Test 2 (with metabolic activation): 0, 33, 100, 333, 1,000, 2,500 and 5,000 µg/plate

Vehicle

DMSO

Remarks - Method

E. coli was not tested. Concentrations for the main tests were chosen on the basis of a preliminary test with two strains.

RESULTS

| Metabolic Activation | Test Substance Concentration (µg/plate) Resulting in: | | | |
|----------------------|---|---------------------------|---------------|------------------|
| | Cytotoxicity in Preliminary Test | Cytotoxicity in Main Test | Precipitation | Genotoxic Effect |
| Absent | > 1,000 | | | |
| Test 1 | | > 1,000 | > 5,000 | negative |
| Test 2 | | > 333 | > 2,500 | negative |
| Present | > 1,000 | | | |
| Test 1 | | > 100 | > 5,000 | negative |

| Test 2 | > 1,000 | > 5,000 | negative |
|-------------------|--|---------|----------|
| Remarks - Results | An increase in mutations was not noted either in the standard plate test or in the pre incubation test in the presence or absence of a metabolising system. | | |
| | The positive and negative controls produced satisfactory responses, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains. | | |
| CONCLUSION | The test substance was not mutagenic to bacteria under the conditions of the test. | | |
| TEST FACILITY | RCC (2000) | | |

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

| | |
|-----------------------|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test. |
| Inoculum | Activated sewage and surface water sludge |
| Exposure Period | 28 days |
| Auxiliary Solvent | None |
| Analytical Monitoring | Biological Oxygen Demand (BOD) |
| Remarks - Method | The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. |

RESULTS

| <i>Test substance</i> | | <i>Sodium acetate</i> | |
|-----------------------|----------------------|-----------------------|----------------------|
| <i>Day</i> | <i>% Degradation</i> | <i>Day</i> | <i>% Degradation</i> |
| 7 | 12 | 7 | 82 |
| 14 | 56 | 14 | 90 |
| 21 | 72 | 21 | 92 |
| 28 | 78 | 28 | 92 |

Remarks - Results All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 4 days (69%). Therefore, the tests indicated the suitability of the inoculum. The degree of degradation of the test substance after 28 days was 78%. As the test substance is surface active, the 10-day window is not applicable. Therefore, the test substance is considered to be readily biodegradable according to the OECD (301 F) guideline.

CONCLUSION The notified polymer is readily biodegradable.

TEST FACILITY Henkel (2001)

C.1.2. Anaerobic biodegradability

| | |
|-----------------------|--|
| TEST SUBSTANCE | Notified polymer |
| METHOD | ECETOC Technical Report No. 28/SS-EN ISO 11734 Water quality – Evaluation of the “ultimate” biodegradability of organic compounds in digested sludge |
| Inoculum | Digested sludge |
| Exposure Period | 60 days |
| Auxiliary Solvent | None |
| Analytical Monitoring | Total Inorganic Carbon (TIC) |
| Remarks – Method | The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. |

RESULTS

| <i>Test substance</i> | | <i>Toxicity control</i> | | <i>Sodium benzoate</i> | |
|-----------------------|----------------------|-------------------------|----------------------|------------------------|----------------------|
| <i>Day</i> | <i>% Degradation</i> | <i>Day</i> | <i>% Degradation</i> | <i>Day</i> | <i>% Degradation</i> |
| 12 | 10.34 | 12 | 9.94 | 12 | 17.51 |
| 21 | 44.94 | 21 | 52.79 | 21 | 79.53 |
| 35 | 70.08 | 35 | 73.40 | 35 | 96.10 |
| 60 | 91.95 | 60 | 89.90 | 60 | 96.56 |

| | |
|-------------------|--|
| Remarks – Results | All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 21 days (79.53%) and reached a degradation plateau (96.56% by 60 days). Therefore, the tests indicate the suitability of the inoculum. The carbon reduction of the toxicity control was in the range of the reference compound, showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after 60 days was 91.95%. Therefore, the test substance is considered to be anaerobically biodegradable according to the ISO (11734) guideline. |
| CONCLUSION | The notified polymer is ultimately and anaerobically biodegradable. |
| TEST FACILITY | CENOX (2012) |

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

| | |
|-----------------------|--|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test and Reproduction Test – Static. |
| Species | <i>Daphnia magna</i> |
| Exposure Period | 48 hours |
| Auxiliary Solvent | None |
| Water Hardness | 96 mg CaCO ₃ /L |
| Analytical Monitoring | Total Organic Carbon (TOC) |
| Remarks - Method | As the test substance is a polymer and UVCB, a TOC analysis was carried out to qualitatively demonstrate the presence of the test substance in test solutions. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. |

RESULTS

| Concentration mg/L | | Number of <i>D. magna</i> | Cumulative Immobilised (%) | |
|--------------------|---------|---------------------------|----------------------------|------|
| Nominal | TOC | | 24 h | 48 h |
| Control | Control | 20 | 0 | 0 |
| 0.625 | 0.90 | 20 | 0 | 0 |
| 1.25 | 1.50 | 20 | 0 | 0 |
| 2.5 | 1.97 | 20 | 0 | 0 |
| 5.0 | 3.32 | 20 | 0 | 60 |
| 10.0 | 5.23 | 20 | 0 | 95 |

| | |
|-------------------|--|
| EC50 | 4.7 mg/L (95% CI 4.0-5.6 mg/L) at 48 hours |
| NOEC | 2.5 mg/L at 48 hours |
| Remarks - Results | All validity criteria for the test were satisfied. The test solutions were not renewed during the 48 h test period. The actual concentrations of the test substance were not measured during the 48 h test period; however, samples of the test solution were taken at the start and end of the 48 h test period for TOC analysis. The 48 h EC50 and NOEC for daphnids were determined to be 4.7 mg/L (95% CI 4.0-5.6 mg/L) and 2.5 mg/L, respectively, based on nominal concentrations. |
| CONCLUSION | The notified polymer is considered to be toxic to aquatic invertebrates. |
| TEST FACILITY | Maxxam (2016) |

C.2.2. Chronic toxicity to aquatic invertebrates

| | |
|-----------------------|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 211 <i>Daphnia magna</i> Reproduction Test – Semi-static. |
| Species | <i>Daphnia magna</i> |
| Exposure Period | 21 days |
| Auxiliary Solvent | None |
| Water Hardness | 1.665-1.764 mmol Ca ²⁺ |
| Analytical Monitoring | Bismuth Active Substance (BiAS) method |
| Remarks - Method | The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. |

RESULTS

| | Test Concentration (nominal; mg/L) | | | | | |
|--|------------------------------------|-----------|-----------|-----------|-----------|-----------|
| | Control | 0.0032 | 0.01 | 0.032 | 0.1 | 0.32 |
| Total No. of Offspring Released by Survived <i>Daphnia</i> | 90 ± 13.6 | 93 ± 12.9 | 89 ± 15.2 | 87 ± 17.8 | 91 ± 7.4 | 96 ± 10.6 |
| Survival | No effect | No effect | No effect | No effect | No effect | No effect |

NOEC ≥ 0.32 mg/L at 21 days

Remarks - Results All validity criteria for the test were satisfied. The test solutions were renewed three times a week (on Mondays, Wednesdays and Fridays) during the 21 d test period. The actual concentrations of the test substance were measured at the start, end and every 2-3 days during the 21 d test period. As measured concentrations were within 20% difference of the nominal concentrations, the nominal concentrations were used. The 21 d NOEC for daphnids was determined to be ≥ 0.32 mg/L, based on nominal concentrations.

CONCLUSION The notified polymer is considered to be potentially harmful to aquatic invertebrates on a chronic basis.

TEST FACILITY Evonik Industries (2007)

C.2.3. Algal growth inhibition test

| | |
|-----------------------|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test – Static. |
| Species | <i>Scenedesmus subspicatus</i> (green alga) |
| Exposure Period | 72 hours |
| Concentration Range | Nominal: 4.27-100 mg/L Actual: 10.53-51.01 mg/L |
| Auxiliary Solvent | None |
| Water Hardness | Not reported |
| Analytical Monitoring | Bismuth Active Substance (BiAS) method |
| Remarks - Method | The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. |

RESULTS

| Biomass | | Growth | |
|----------------------|--------------|----------------------|--------------|
| EC50 mg/L at 72 h | NOEC mg/L | EC50 mg/L at 72 h | NOEC mg/L |
| 12 | 4.3 | 71 | 4.3 |

| | |
|-------------------|--|
| Remarks - Results | All validity criteria for the test were satisfied. The test solutions were not renewed during the 72 h test period. The actual concentrations of the test substance were measured every 24 hours during the 72 h test period. As measured concentrations were within 20% difference of the nominal concentrations, the nominal concentrations were used. The 72 h EC50 and NOEC for algae were determined to be 71 mg/L and 4.3 mg/L, respectively, based on nominal concentrations. |
| CONCLUSION | The notified polymer is considered to be harmful to algae. |
| TEST FACILITY | Henkel (2000) |

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