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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Ecosurf LF series

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1417	Dow Chemical (Australia) Limited & IMCD Australia Limited	Ecosurf LF series	Yes	≤500 tonnes per annum	Component of coatings, adhesives and industrial cleaning products

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 for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Acute toxicity (Category 4)	H302 - Harmful if swallowed
Eye Irritation (Category 2A)	H319 – Causes serious eye irritation

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R22 Harmful if swallowed
R36 Irritating to eyes

The environmental hazard classification according to the *Globally Harmonised System for the 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.

Hazard classification	*Hazard statement*
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 assessed use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Acute toxicity (Category 4): H302 – Harmful if swallowed
  - Eye irritation (Category 2A): H319 – Causes serious eye irritation

- The following should be used for products/mixtures containing the notified polymer:
  - Conc. ≥25%: H302, H319
  - ≥10% Conc. <25%: H319

- The Delegate (and/or the Advisory Committee on Chemicals Scheduling) should consider the notified chemical for listing on the SUSMP.

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 and end-use processes:
  - Enclosed, automated processes, where possible
  - Ventilation system including local exhaust ventilation
  - Spray application of coatings in spray booths or other adequately ventilated areas.

- 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 during reformulation and end-use processes:
  - Avoid contact with skin and eyes
  - Avoid inhalation
  - Use in ventilated areas

- 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 processes:
  - Coveralls, impervious gloves, goggles
  - Respiratory protection (during spray application of coatings and if ventilation is inadequate)

  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 *National Guidance Material for Spray Painting* (NOHSC, 1999) or relevant State and Territory Codes of Practice.

- 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 for the 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

- The notified polymer should be disposed of to landfill.

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 proposed concentration of the notified polymer in end-use products increases or is intended to increase;
- the notified polymer is proposed to be used in products that may be applied by members of the public by spray;
- information on the toxicity of the notified polymer following inhalation or repeated exposure becomes available;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of coatings, adhesives and industrial cleaning products, or is likely to change significantly;
- the amount of polymer being introduced has increased from 500 tonnes per annum, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

(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)
Dow Chemical (Australia) Limited (ABN 72 000 264 979)
541-583 Kororoit Creek Road
ALTONA VIC 3018

IMCD Australia Limited (ABN 44 000 005 578)
Level 1, 372 Wellington Rd
MULGRAVE VIC 3170

NOTIFICATION CATEGORY
Standard: Synthetic polymer with Mn <1000 Da (more than 1 tonne per year).

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, polymer constituents, residual monomers/impurities, additives/adjuvants, use details, import volume and identity of analogue polymers.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Acute inhalation toxicity, skin sensitisation, repeated dose toxicity and all physico-chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Ecosurf LF series (neat notified polymer)

MOLECULAR WEIGHT
>500 Da

3. COMPOSITION

DEGREE OF PURITY >99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Pale yellow liquid

Property	Value	Data Source/Justification
Pour Point	-22 – 6 °C	Product information sheet
Boiling Point	Not determined	The notified polymer decomposes at > 150 °C.
Density	993 – 1013 kg/m^3 at 25 °C	Product information sheet
Vapour Pressure	2.27x10^{-16} kPa at 20 °C	Estimated (Episuite 2011)
Water Solubility	~ 25 – 35 × 10^{-3} g/L	Measured. The typical critical micelle concentration for the notified polymer was reported, however no study report was provided.
Hydrolysis as a Function of pH	Not determined	Not expected to hydrolyse at environmental pH (4 – 9)
Partition Coefficient (n-octanol/water)	log Kow = 2.85 – 4.30	MSDS. The values are consistent with QSAR calculations for representative species of the notified polymer - log Kow = 1.55 – 4.33 (KOWWIN v1.68, US EPA 2011). However, the results should be treated with caution as the notified polymer is a surfactant and is expected to accumulate at the phase interface of octanol and water.
Adsorption/Desorption	Not determined	Expected to partition to surfaces from water based on its surface activity.
Dissociation Constant	Not determined	Contains no dissociable functional groups.
Flash Point	193 °C (closed cup)	Estimated based on analogue. Product information sheet.
Flammability	Not determined	Based on the flash point the notified polymer is not expected to be flammable.
Autoignition Temperature	Not determined	Based on the flash point the notified polymer is not expected to autoignite under normal conditions of use.
Explosive Properties	Not determined	Based on its structure, the notified polymer is not expected to be explosive.
Oxidising Properties	Not determined	The notified polymer is not expected

to have oxidising properties.

DISCUSSION OF PROPERTIES

Reactivity

Contact with oxidising agents and strong acids/bases should be avoided due to risk of reactivity; however, under normal conditions of use the notified polymer is considered stable.

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 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 neat (>99% purity) and reformulated into end-use products that will contain the notified polymer at <1% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	30-100	100-300	100-300	300-500

PORT OF ENTRY

Sydney, Melbourne, Adelaide, Brisbane and Perth.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported into Australia in 200L polyethylene drums and transported by road to bunded chemical warehouses where it will be stored until distribution to customers for reformulation. The finished products containing the notified polymer will be packaged in containers of various sizes and materials and transported by road or rail to end users.

USE

The notified polymer is a non-ionic surfactant that will be used at up to 1% concentration in products for a range of applications, including coatings (40% of total import volume), industrial hard surface cleaners (25%), food and non-dairy beverage cleaning (25%), inks (5%), and adhesives (5%).

OPERATION DESCRIPTION

Reformulation

Coatings, inks and adhesives

The notified polymer will be transferred by automated processes into mixing vessels and combined with resin, pigments, solvents, fillers and other additives to produce end-use products. Sampling will be done to ensure quality of the products produced. The final products (containing <1% notified polymer) will be repackaged into cans, pails, drums or totes via dedicated closed transfer lines for distribution.

Industrial hard surface cleaning products

The notified polymer will be added via automated lines with other ingredients to large stainless steel tanks (150-250,000 L) for blending (1-4 hours) at ambient temperature. The final products will be then packed into smaller containers (1-205 L) via pneumatic or gravity driven processes. Sampling of the products via pipette will occur on a regular basis for quality purposes. The blending tank and filling lines will be routinely flushed with water for cleaning.

Food and non-dairy beverage cleaning products

The notified polymer will be blended with other ingredients in closed blending vessels. The end-use products (containing <1% notified polymer) will then be gravity fed into Reconditioned High Density Polyethylene (RHDP) drums. These products will be sampled for quality prior to the distribution of drums to customers.

End use

Coatings

End-use products containing the notified polymer (<1%) will typically be applied to various substrates by

professional personnel, predominantly by spray (~99%). This process will be conducted in designated spray booths using automated (robotic) or manual (spray gun) methods. Approximately 1% of applications will involve a roller or brush.

(DIY) coatings
A small proportion of the notified polymer (<5% total import volume) may be sold to the public as a component (<1%) of decorative paints. Paint products are expected to be applied to surfaces by rollers or brushes. Applicators used will be washed with water.

Inks
Inks containing the notified polymer (<1%) will be transferred, via automated lines, from drums to commercial printing equipment and stored in enclosed vessels. The inks will be applied to paper and plastic substrates.

Adhesives
Products containing the notified polymer (<1%) are expected to be applied to a range of substrates using a brush or roller.

Industrial hard surface cleaning products
Cleaning products containing the notified polymer (<1%) will often be diluted (1:5 to 1:200) for final use. Instructions for dilution are expected to be clearly marked on the product label or products. The diluted solution will be applied through a variety of methods including direct wiping using an applicator (e.g. cloth), by spray, via liquid stream from a squeeze bottle, by machine, or by soaking.

Food and non-dairy beverage cleaning products
Products containing the notified polymer (<1%) will be used to clean equipment including pipelines, vats and fillers in breweries, wineries and food/beverage processing plants. The products will often be diluted further with water during cleaning, depending on the type and size of surface. Once cleaned, product residues will be rinsed from equipment surfaces with potable water.

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)*
COATING, INKS AND ADHESIVES		
Waterside workers	4	50
Storage and transport personnel	5	150
Formulation personnel	1-3	100
Applicators	0.5-6	60
INDUSTRIAL HARD SURFACE CLEANING PRODUCTS		
Waterside workers	4	50
Storage and transport personnel	5	150
Formulation personnel	0.5-2	100
End users	8	240
FOOD AND NON-DAIRY BEVERAGE CLEANING		
Waterside workers	4	50
Storage and transport personnel	5	150
Formulation personnel	1-3	100
End users	0.5-6	60

EXPOSURE DETAILS

Transport and storage

It is anticipated that transport and warehouse/store personnel would only be exposed to the notified polymer in the unlikely event of an accident.

Reformulation
Reformulation into the finished products will occur at various customer sites and dermal and ocular exposure to the notified polymer (at up to >99%) may occur during addition to the mixing tanks from storage drums if manual processes are used, or while connecting/disconnecting lines. Exposure may also occur during routine testing and cleaning of equipment. However, exposure is expected to be limited by the use of Personal Protective Equipment (PPE) (including safety glasses, impervious gloves and protective clothing).

End use
Coatings
Exposure to the notified polymer may occur when applying coatings containing the notified polymer at <1% concentration by brush, roller or spray and while cleaning equipment. The primary routes of exposure are dermal, ocular and inhalation during spray application. However, exposure should be limited as the coatings will be applied predominantly by professionals who are expected to use appropriate PPE (including respiratory protection where necessary) and spray applications are expected to be conducted in designated spray booths or well ventilated areas. Once the coatings are dried, the notified polymer will be trapped within the matrix and will not be bioavailable.

Inks and Adhesives
There is potential for dermal exposure to the notified polymer at concentrations of <1% when applying the adhesives by brush or roller, and when connecting and disconnecting transfer lines to printers. The expected use of PPE by these workers should limit exposure.

Industrial hard surface cleaning
Exposure to the notified polymer when using cleaning products containing the notified polymer at <1% is expected to be widespread, frequent and extensive. The primary routes of exposure will be dermal, ocular and inhalation during application by spray. The expected use of PPE by these workers should limit exposure.

Food and non-dairy beverage cleaning
Exposure to cleaning products containing the notified polymer at <1% concentration is expected to be widespread, frequent and extensive. Exposure time is expected to last less than 1 minute, after which the solution will be rinsed from the surface and drained away. The primary routes of exposure will be dermal and ocular. The expected use of PPE by these workers should limit exposure

6.1.2. Public Exposure
Dermal exposure to the notified polymer may occur when applying decorative paints containing <1% notified polymer by brush and roller. There is not anticipated to be any further direct exposure to the notified polymer as all other products are for professional use only. The public may have widespread exposure to dried coatings, inks and adhesives containing the notified polymer (<1%), however the polymer will be cured in the matrix and will be unavailable for exposure. The public may also be exposed through contact with hard surfaces that have been cleaned with products containing the notified polymer (<1%). Such exposure is expected to be at most occasional, due to the industrial nature of such surfaces.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the notified polymer (or analogue polymer) are summarised in the table below. Details of these studies can be found in Appendix A.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 550-2000 mg/kg bw; harmful
Rat, acute oral toxicity	LD50 >2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	irritating
Human, skin sensitisation – RIPT (10%)*	no evidence of sensitisation
Rat and dog, repeat dose oral toxicity – 90 days*	NOAEL (rats) 62.5-125 mg/kg bw/day NOAEL (dogs) 154-354 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration	non genotoxic

Rat, reproductive and developmental toxicity*	NOEL (parental toxicity) 60 mg/kg bw/day NOAEL (reproductive/developmental toxicity) ≥470 mg/kg bw/day

*Study performed on an analogue polymer

Toxicokinetics, metabolism and distribution.
Based on the water solubility (25-35 x 10^{-3} g/L), partition coefficient (log Kow = 2.85-4.30) and surfactant nature of the notified polymer, absorption across the gastrointestinal tract and dermal absorption may occur. However, the extent of absorption may be limited by the relatively high molecular weight (<1000 Da) of the notified polymer. The notified polymer may be absorbed across the respiratory tract.

Acute toxicity.
The notified polymer was found to be harmful in an acute oral toxicity study in rats. In the main study 3/4 animals treated at 2000 mg/kg bw died within 1-day of dosing, with notable signs of toxicity in these animals including hypoactivity, hunched posture and/or ano-genital staining. Red discolouration of the intestines was noted at necropsy in the animals that died during the observation period. No abnormalities were noted at necropsy in animals treated at the lower doses (550 and 175 mg/kg bw).

In a second acute oral toxicity study, the notified polymer was determined by the study authors to have an LD50 >2000 mg/kg bw. However, it is noted that 2/5 animals tested at 2000 mg/kg bw died within 1-day of dosing, with hypoactivity and/or ano-genital staining noted in these animals prior to death. Red discolouration of the intestines or lungs was noted at necropsy in the animals that died during the observation period.

The notified polymer was found to be of low toxicity (LD_{50} of >2000 mg/kg bw) in an acute dermal toxicity study in rats. There were no mortalities, adverse clinical signs or adverse effects on organs at this dosage level.

There were no data submitted on the acute inhalation toxicity potential of the notified polymer.

Irritation and Sensitisation.
The notified polymer was found to be slightly irritating to the skin of rabbits, with very slight erythema noted in all animals. The effects cleared within 72 hours. The irritation scores did not warrant classification of the polymer as a skin irritant.

The notified polymer was found to be an eye irritant in rabbits, with corneal opacity, iridial inflammation and conjunctival effects observed (with eyes appearing normal by day 14 of the observation period). On day 6 of the eye irritation study, one animal was noted to have died. The study authors noted that there were no clinical signs of toxicity observed in this animal prior to its death, however red discolouration of the lungs and intestines were noted at necropsy. While there is insufficient evidence to determine the cause of death in the rabbit, considering a lack of clinical symptoms in the rabbit leading up to death in combination with a lack of similar effects in studies on analogous surfactants, as reported by the notifier, the death is unlikely to be treatment related.

No skin sensitisation data were provided to enable hazard identification. However, based on the absence of structural alerts, the notified polymer is not expected to be a skin sensitiser. In addition, it is noted that there was no evidence of sensitisation in a human repeat insult patch test that was conducted on an analogue polymer (at 10% concentration).

Repeated Dose Toxicity.
No repeated dose toxicity data were submitted for the notified polymer. However, reports from three studies (90 day feeding studies) conducted on an analogue polymer in rats (treated at 62.5, 125, 250 and 500 mg/kg bw/day) and beagle dogs (treated at 82, 154 and 354 mg/kg bw/day) were submitted.

While limited details were provided (and/or limited parameters were tested), the results indicated statistically significant mean body weight gain reductions in male and female rats dosed with the test substance at ≥125 mg/kg bw/day. The absolute liver and kidney weights were statistically significantly decreased in rats dosed with the test substance at 500 mg/kg bw/day; however, the relative weights were not significantly reduced. The NO(A)EL in rats was established by the study authors as between 62.5 and 125 mg/kg bw/day.

In dogs, doses of 354 mg/kg bw/day resulted in severe mean body weight losses and the subsequent halting of treatment at week 6. These animals re-gained weight on the control diet by the study completion. Statistically significantly reduced haemoglobin was noted in one dog receiving the test substance at 354 mg/kg bw/day.

Hydrocephalus was noted in 1 male and 2 female dogs treated with the test substance at 354 mg/kg bw/day, however, this was considered to be non-treatment related by the study authors, on the basis that it is a common lesion in dogs (although in this study, control group dogs did not have any evidence of hydrocephalus). The NO(A)EL in dogs, for the notified polymer has been estimated to between 150 and 350 mg/kg bw/day.

Genotoxicity
The notified chemical was not mutagenic in a bacterial reverse mutation study and was not clastogenic in an in vitro mammalian chromosome aberration test.

Toxicity for reproduction.
No reproductive and developmental toxicity data were submitted for the notified polymer. A reproductive and developmental toxicity study that was conducted on an analogue polymer in rats (treated at 60, 168 and 470 mg/kg bw/day) was submitted. The results of the study indicated that there were no adverse effects in foetuses, but there was some systemic toxicity in male and female adults (reductions in mean body weight, food consumption and clinical signs were noted) at doses ≥168 mg/kg bw/day. Therefore, a NOEL for parental toxicity of 60 mg/kg bw/day was established and a NOAEL for reproductive/developmental toxicity was established as ≥470 mg/kg bw/day.

Health hazard classification
Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Acute toxicity (Category 4)	H302 - Harmful if swallowed
Eye Irritation (Category 2A)	H319 – Causes serious eye irritation

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R22 Harmful if swallowed
R36 Irritating to eyes

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
During reformulation workers will handle the notified polymer at ≤100% concentration. Workers will also be exposed to products containing the notified polymer at concentrations of <1%, during end use. While the notified polymer is considered to be harmful to human health via the oral route, ingestion is unlikely under the occupational settings described. However, the notified polymer is an eye irritation hazard to workers in occupational settings. In addition, potentially adverse effects following repeated inhalation exposure to the notified polymer, particularly during spray applications, cannot be ruled out, noting that only limited information on the repeated dose toxicity potential of the notified polymer is available. Therefore, caution should be exercised by workers when repeatedly handling the notified chemical during reformulation and end use processes (in particular, during spray application processes).

Provided that control measures (e.g. containment and/or adequate ventilation and appropriate PPE, such as goggles, impervious gloves, coveralls and respiratory protection, as applicable) are in place to minimise worker exposure to the notified polymer during reformulation and end use processes, the risk to the health of workers from exposure to the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
The public may be exposed to the notified polymer when applying the paint containing <1% notified polymer by brush or roller. Spray application is not anticipated, as this requires the use of special tools. DIY use is expected to be infrequent and users may wear some PPE to minimise exposure. In addition, painting is expected to occur in ventilated environments.

The public may come into contact with products to which the coatings, adhesives and inks containing the notified polymer have been applied. However, the polymer will be bound in a matrix and will be unavailable

for exposure.

Therefore, under the proposed use scenarios, the risk to public health 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

Coating, inks and adhesives.

During reformulation, an estimated 0.1% of the annual import volume of notified polymer may be released from accidental spills or leaks. In the unlikely event that a major spill occurs, the notified polymer is expected to be contained by bunding and collected for disposal to landfill. Residues of the notified polymer that will remain in the empty storage containers are estimated to account for up to 0.1% of the annual import volume. Small amounts of the notified polymer (estimated at 0.1%) may be lost in washings from cleaning of the manufacturing equipment. These small quantities are likely to be recycled internally but may be released to sewer.

Industrial hard surface cleaning products

During reformulation, incidental spillage or wastes are expected to be contained and soaked up with absorbent material before being transported off-site to an approved industrial facility for disposal to landfill. The transferring/pumping of the notified polymer into blending vessels and the packaging of the mixture into the final consumer products will be automated. The residues in the transfer hose and dip pipe are expected to be washed to effluent. It is expected that up to 0.1% of the total import volume of the notified polymer would be discharged to effluent through the washout procedures. It is estimated that the maximum residue of notified polymer in the empty import containers will amount to 0.1%. The residues are expected to be discharged to effluent via drum recyclers.

Food and non-dairy beverage cleaning products

Limited environmental release is anticipated during the production of the products containing the notified polymer, since the formulation involves mixing of ingredients in a closed system at ambient temperature. Wastewater effluent is expected to be flushed to an onsite wastewater pit where the water will be treated prior to disposal to sewer. Any ingredients remaining on the mixer vessel walls, product pipelines or package filter units will be rinsed to a wastewater drain. It is estimated that up to 0.1% of the notified polymer will be released to the aquatic environment due to flushing of equipment and up to 0.1% will be released as residues in empty import containers.

RELEASE OF CHEMICAL FROM USE

Coatings, inks and adhesives

The notified polymer is anticipated to be used in coatings, inks and adhesives in the proportions of 40%, 5% and 5% of the total import volume, respectively. Approximately half the ink containing notified polymer will be applied to paper. During industrial spray application of formulated coatings, the losses from overspray are predicted to be ≤20%. These releases are expected to be captured by standard engineering controls in spray booths for disposal to landfill. Approximately 0.1% per annum of the imported notified polymer may be lost in washings from cleaning of industrial application equipment. Formulation sites are likely to have primary treatment processes that will handle waste before wastewater is discharged into the municipal system. Approximately 52% of the annual importation volume used in coatings will be available for public use, and some release of the notified polymer to waterways may occur as a result of DIY applications. These releases would result from cleaning the application equipment (i.e. brush or roller) with the residues likely to be washed down the drain. Up to 5% of the volume available to the public, equating to 1% (5% × 52% × 40%) of total import volume of notified polymer, is predicted to be released to sewers in a disperse manner across Australia. Any residues present in the end-use containers are expected to be disposed of in household garbage or at dedicated waste deposits.

industrial hard surface cleaning products

Approximately 25% of the annual import volume of the notified polymer will be used in cleaning products for industrial purposes only. The majority of the notified polymer used in cleaning products will be discharged to sewer. Therefore, release is expected to be widespread and include both metropolitan and country areas. Small

amounts of notified polymer may remain in empty product containers or cleaning rags, and disposed of to landfill.

Food and non-dairy beverage cleaning products
Approximately 25% of the annual import volume of the notified polymer will be used in food and non-dairy beverage processing plant cleaning. Used cleaning product containing the notified polymer is expected to be discharged to a wastewater storage reservoir. It is assumed that all of the notified polymer in the reservoirs will be eventually released to sewer.

RELEASE OF CHEMICAL FROM DISPOSAL
Coating, inks and adhesives
Printed paper containing the notified polymer is expected to be disposed of to landfill or recycled. Recycling of treated paper may result in the release of a proportion of the notified polymer to the aquatic compartment. Waste paper will be re-pulped using a variety of chemical treatments, which result in fibre separation and ink detachment from the fibres. The aqueous wastes are expected to be released to sewers. It is assumed that approximately 50% of the printed paper (1.25% of total imported notified polymer) is assumed to enter paper recycling and a minor proportion of the ink may be recovered during recycling in the sludge. Any quantity of notified polymer recovered with sludge during the recycling process is expected to be disposed of to landfill.

As a result of DIY use and industrial spills, some release of the notified polymer to drains and, hence, sewage treatment works may occur.

Industrial hard surface cleaning products
Unused liquid wastes of the notified polymer are likely to be disposed of to landfill.

Food and non-dairy beverage cleaning products
After use, empty drums will be flushed with water prior to being sent to the drum recycler. Therefore, there is unlikely to be significant residual product in the containers. The smaller end use containers, if not recycled, would most likely be disposed of to landfill.

7.1.2. Environmental Fate
Approximately half (53.0%) of the notified polymer is expected to be released to sewer due to reformulation activities (0.7%) and when used in industrial hard-surface cleaning (25%), food and non-dairy beverage processing plant cleaning (25%), coatings (1%) and inks (1.25%). The results of the ready biodegradability test indicate that although the notified polymer did not meet the strict criteria for ready biodegradability, it is expected to be rapidly removed from sewage treatment plant (STP) influent via biodegradation. A small proportion of the notified polymer may be discharged to receiving waters in treated effluent where the notified polymer is expected to disperse and degrade. A high proportion of the notified polymer that is not biodegraded in STPs is expected to sorb to sludge based on its surfactant properties. Notified polymer bound to sewage sludge is expected to be disposed of to landfill or used for soil remediation where it is expected to have limited mobility based on its surface activity. In landfill, the notified polymer is expected to eventually degrade by abiotic and biotic processes to form water and oxides of carbon. Bioaccumulation is not likely as the notified polymer is readily biodegradable and belongs to a class of chemicals with low bioaccumulation (Madsen et al., 2001). For the details of the environmental fate study please refer to Appendix B.

7.1.3. Predicted Environmental Concentration (PEC)
A predicted environmental concentration (PEC) was calculated assuming that 53% of the total import volume of notified polymer will be released to sewers. The removal of the notified polymer from sewage treatment plant (STP) influent was estimated to be ≥97% based on literature studies on close analogues of the notified polymer (Exempt Information). Based on its predominately industrial use, it is assumed the release of the notified polymer will occur over 260 days per annum into the total Australian effluent volume corresponding to a working week of 5 days per week.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	500,000	kg/year
Proportion expected to be released to sewer	53%	
Annual quantity of chemical released to sewer	265,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1019	kg/day

Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	97%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	6.76	µg/L
PEC - Ocean	0.68	µg/L

The notified polymer that is not removed from waste water during STP processes may be released to the environment in STP effluent. STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/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 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 6.76 µg/L may potentially result in a soil concentration of approximately 45 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 225 µg/kg and 451 µg/kg, respectively. However, due to the expected rapid biodegradability of the notified polymer, these calculated values represent theoretical maximum concentrations only.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations and a Quantitative Structure Activity Relationship (QSAR) calculation conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)	LC50 ≥1.46 mg/L*	Toxic to fish
Daphnia Toxicity (48 h)	EC50 = 4.22 mg/L	Toxic to invertebrates
Algal Toxicity (72 h)	E_rC50 = 1.25 mg/L	Toxic to algae
	NOEC = 0.375 mg/L	Harmful to algae with long lasting effects

*Calculated by ECOSAR v1.0 (non-ionic surfactant class; US EPA, 2011)

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified polymer is considered to be acutely toxic to fish, aquatic invertebrates and algae. Based on the acute toxicity to aquatic organisms the notified polymer is formally classified for the aquatic environment under the GHS as "Acute category 2; Toxic to aquatic life". One adequate chronic toxicity endpoint was available (algal NOEC). Therefore, the long-term classification for the notified polymer was determined based on the most stringent outcome by comparing the long-term hazard classification using either the acute or chronic data. Analogue bioconcentration factor (BCF) data indicated that the notified polymer is not expected to be bioaccumulative and therefore the notified polymer cannot be classified for long-term hazard using acute endpoints and the n-octanol/water partition coefficient (log Kow). The long-term hazard classification is therefore based on classification by the chronic endpoint and hence the notified polymer is formally classified under the GHS as "Chronic category 3; Harmful to aquatic life with long lasting effects".

7.2.1. Predicted No-Effect Concentration

The endpoint of the most sensitive species (algae) determined from ecotoxicological studies submitted for the notified polymer was used to calculate the Predicted No-Effect Concentration (PNEC). An assessment factor of 100 was used as experimental endpoints for two trophic levels and a reliable estimated endpoint for a third trophic level was available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 Algae	1.25	mg/L
Assessment Factor	100	
PNEC:	12.5	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	6.76	12.5	0.54
Q - Ocean	0.676	12.5	0.054

The Risk Quotient (Q = PEC/PNEC) has been calculated to be <1 for the aquatic environment, which indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters based on its maximum annual import volume and proposed use patterns in the proportions assessed. The notified polymer has a low potential for bioaccumulation and is unlikely to be persistent in the environment. On the basis of the PEC/PNEC ratio, maximum annual use volume and assessed use patterns, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.
Species/Strain	Rat/Fischer 344
Vehicle	None
Remarks - Method	No significant protocol deviations. In a preliminary limit test, 3/4 females treated at 2000 mg/kg bw died within 2 days of dosing. In the main test, an additional 8 females were treated sequentially at 175 (1 animal), 550 (total 3 animals) or 2000 (total 4 animals) mg/kg bw.
RESULTS	
LD50	Between 550 and 2000 mg/kg bw
Remarks - Results	Of all animals dosed with 2000mg/kg bw (4 in preliminary test and 4 in main test), 6 died within 2 day post-dosing. Clinical signs of toxicity before death in the main test animals were hypoactivity, hunched posture and/or ano-genital staining (these signs and diarrhoea and/or reduced fecal volume were also noted in the animals that died during the preliminary test). Surviving animals recovered from the same symptoms by day 5. Red discolouration of the intestines was noted at necropsy in all animals that died during the observation period. One animal treated at 550 mg/kg bw had ano-genital staining and reduced fecal volume up to 1 day post dosing. No abnormalities were noted at necropsy in animals treated at 550 or 175 mg/kg bw.
CONCLUSION	The notified polymer is harmful via the oral route.
TEST FACILITY	Eurofins (2009a)

A.2. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.
Species/Strain	Rat/Fischer 344
Vehicle	None
Remarks - Method	No significant protocol deviations. An initial limit dose of 2000 mg/kg bw was administered to a single female. Based on the absence of mortality in this animal, an additional 4 females were treated sequentially at 2000 mg/kg bw.
RESULTS	
LD50	The study authors considered the LD50 to be >2000 mg/kg bw.
Remarks - Results	2/4 animals dosed with 2000 mg/kg bw died within 1 day post-dosing. Clinical signs of toxicity before death were hypoactivity and ano-genital staining. Surviving animals exhibited the same effects and/or reduced fecal volume up to day 4. Red discolouration of the intestines or lungs was noted at necropsy in the animals that died during the observation period. No abnormalities were noted at necropsy in the remaining animals.
CONCLUSION	The notified polymer was of low toxicity via the oral route, under the

conditions of the test.

TEST FACILITY Eurofins (2009b)

A.3. Acute toxicity – dermal

TEST SUBSTANCE Notified polymer

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain Rat/Fischer 344
Vehicle None
Type of dressing Semi-occlusive
Remarks - Method No significant protocol deviations.

RESULTS
LD50 >2000 mg/kg bw
Remarks - Results No mortalities, signs of toxicity, or adverse effects in organs were reported at the dose level of 2000 mg/kg bw.

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

TEST FACILITY Eurofins (2009c)

A.4. Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Vehicle None
Observation Period 72 hours
Type of Dressing Semi-occlusive
Remarks - Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.3	0.3	0.7	1	<72 hours	0
Oedema	0	0	0	0	0	0

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

Remarks - Results Very slight erythema was noted in all treated animals (at up to and/or including the 48-hour observation point). The effects cleared by 72 hours. Slight desquamation was noted in a single treated animal at the end of the observation period.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY Eurofins (2009d)

A.5. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3

Observation Period 72 hours
Remarks - Method No significant protocol deviations.

At the 24-hour observation (and at various observation points thereafter), a 2% fluorescein solution was instilled into both eyes of each animal.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2	1.3	1.3	2	<7 days	0
Conjunctiva: chemosis	1.3	1	1	2	<7 days	0
Conjunctiva: discharge	2	1.3	1.3	2	<14 days	0
Corneal opacity	1	0.7	0.7	1	<7 days	0
Iridial inflammation	1	1	0.7	1	<7 days	0

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

Remarks - Results One animal died on day 6. Discolouration of the lungs and intestines was noted in this animal at necropsy (the study authors note that there were no clinical signs observed in the animal prior to its death). With the exception of soft feces, which was noted on days 3-6 in 1 surviving rabbit, no other clinical signs were reported.

All animals exhibited corneal opacity, iritis and conjunctival irritation. The eyes of both surviving animals appeared normal by the end of the 14 day observation period.

CONCLUSION The notified polymer is irritating to the eye.

TEST FACILITY Eurofins (2009e)

A.6. Skin sensitisation – human volunteers

TEST SUBSTANCE Analogue polymer (applied at 10% concentration)

METHOD Repeated insult patch test with challenge.
Study Design Induction Procedure: 15 induction applications were made to the same site on alternate days. The skin (arm or back) was exposed to patches containing the test substance for 24 hrs. The patches were then removed and any reactions recorded.
Rest Period: 14 days.
Challenge Procedure: 1 challenge application to the same site, followed by skin assessment.
Study Group 50 (sex and age unknown)
Vehicle Distilled water
Remarks - Method The patches (unspecified size) contained 0.5 mL of test substance.
Full study report not provided.

RESULTS
Remarks - Results No skin reactions were noted following the induction and challenge applications.

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

TEST FACILITY IBL (1965)

A.7. Repeat dose toxicity

TEST SUBSTANCE Analogue polymer

METHOD	Repeated Dose 90-Day Oral Toxicity Study in Rodents and Dogs.
Species/Strain	Rat/Harlan-Wistar and Dog/Beagle
Route of Administration	Oral – diet
Exposure Information	Total exposure days: 90 days Dose regimen: 7 (rats) or 5 (dogs) days per week
Remarks - Method	Rats: due to a lack of effects in rats treated at an initial dose level of 15.6 mg/kg bw/day, the dose was increased to 500 mg/kg bw/day (after ~3 weeks) for the remainder of the study. Dogs: administration of the test substance was ceased in dogs receiving 350 mg/kg bw/day after 6 weeks, due to significant weight loss in these animals. The dogs then received the control diet until the completion of the study. Full study report not provided.

RESULTS

Rats

Group	*Number and Sex of Animals (M/F)*	*Dose mg/kg bw/day*	*Mortality (M/F)*
I	10/10	0	1/0
II	10/10	62.5	0/0
III	10/10	125	0/0
IV	10/10	250	1/0
V	10/10	500	0/0

Dogs

Group	*Number and Sex of Animals (M/F)*	*Dose mg/kg bw/day*	*Mortality*
I	3/3	0	0/0
II	3/3	82	0/0
III	3/3	154	0/0
IV	3/3	354	0/0

Mortality and Time to Death

One control rat and one rat dosed with the test substance at 250 mg/kg bw/day died. Both animals exhibited clinical signs of pneumonia and the deaths were considered by the study authors not to be treatment related.

No mortalities were noted in the dogs during the study.

Clinical Observations

Mean body weights were statistically significantly reduced in males dosed with the test substance at 125, 250 and 500 mg/kg bw/day and females dosed with 250 and 500 mg/kg bw/day up to day 90. Mean diet consumption was also reduced in females at the same dosage levels.

Dogs receiving the test substance at 354 mg/kg bw/day had a significantly reduced mean body weight up to week 6. Thereafter, the dogs were only fed the control diet and weight gain returned to normal by the study completion. There were no significant reductions in mean body weight noted in dogs at the lower dosage levels.

Laboratory Findings – Clinical Chemistry, Haematology

There were no tests conducted on these parameters in rats.

Dogs receiving the test substance at 354 mg/kg bw/day had statistically significantly reduced haemoglobin at week 12 of the study. No other significant effects on clinical chemistry or haematology parameters were noted.

Effects in Organs

Only the liver and kidneys of the rats were weighed and the abdominal/thoracic organs examined. Mean absolute liver and kidney weights were statistically significantly reduced in females dosed with the test

substance at 500 mg/kg bw/day, however, the relative weights were not significantly reduced in any dose group. There were some sporadic histopathological effects in males and females. However, the study authors considered these results to be non-treatment related (there were no significant variances from control values and/or dose-response relationships were not evident).

Only the liver and kidneys of the dogs were weighed and the abdominal/pleural and cranial organs examined. Hydrocephalus was noted in 1 male and 2 female dogs dosed with the test substance at 354 mg/kg/bw day. However, this effect was not considered to be treatment related by the study authors because, although not found in the control animals in this study, they note that it is a common lesion in dogs.

Remarks – Results
The palatability of the feed containing the test substance was not investigated and the effect of this on the reduction in weight gain is unknown.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) in rats was established by the study authors as between 62.5 and 125 mg/kg bw/day, based on clinical effects noted at doses of 125, 250 and 500 mg/kg bw/day.

The NOAEL in dogs was established by the study authors as between 154 and 354 mg/kg bw/day, based on the clinical and haemotological effects that were noted at 350 mg/kg bw/day.

TEST FACILITY MI (1967)

A.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Aroclor 1254-induced rat liver (S9 fraction).
Concentration Range in Main Test	a) With metabolic activation: up to 5000 µg/plate b) Without metabolic activation: up to 5000 µg/plate
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations. Initial toxicity (Test 1) and confirmatory mutagenicity (Test 2) assays were conducted. Vehicle and positive controls were used in parallel with the test material. As unacceptable positive control values were obtained for strains TA98 and WP2uvrA (in the absence of metabolic activation), additional confirmatory tests were conducted in the relevant strains (with the results incorporated into Test 2).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥500	-	Negative
Test 2	≥150	-	Negative
Present			
Test 1	≥500	-	Negative
Test 2	≥1500	-	Negative

Remarks - Results No precipitation was observed at any of the concentrations tested with or without metabolic activation. Toxicity to the tested strains was observed in both the initial and confirmatory tests.

No significant increases in the frequency of revertant colonies were noted for any of the bacterial strains, either with or without metabolic activation.

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

CONCLUSION The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY BioReliance (2009)

A.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified polymer

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.

Species/Strain	Rat/Sprague-Dawley
Cell Type/Cell Line	Lymphocytes.
Metabolic Activation System	Aroclor 1254-induced rat liver (S9 fraction).
Vehicle	Distilled water
Remarks - Method	A preliminary toxicity study was performed (without metabolic activation) at concentrations 312.5-5000 µg/mL. The study authors noted that lysis of the cells was evident (~1 hour after treatment) at ≥625 µg/mL. Vehicle and positive controls were used in parallel with the test material.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1a	0, 6.25, 12.5, 25, 50, 100, 200, 300	4 hours	24 hours
Test 1b	0, 3.13, 6.25, 12.5, 25, 50, 100, 200, 300	24 hours	24 hours
Test 2a	0*, 2*, 5, 10*, 15, 20*, 25, 30, 35, 40	4 hours	24 hours
Test 2b	0*, 0.5, 1*, 2, 3*, 4, 5*, 6, 7, 8	24 hours	24 hours
Present			
Test 1	0, 12.5, 25, 50, 100, 200, 300, 500	4 hours	24 hours
Test 2	0*, 10, 20*, 40, 50*, 60, 70*, 80, 90	4 hours	24 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1a	≥25	-	-
Test 1b	≥6.25	-	-
Test 2a	≥20	-	Negative
Test 2b	≥5	-	Negative
Present			
Test 1	≥100	-	-
Test 2	≥70	-	Negative

Remarks - Results The study authors considered that the desired level of cytotoxicity was not achieved under the Test 1 conditions. Therefore, the study was repeated (Test 2), with a focus on lower concentrations.

No significant increases in the number of cells with aberrations were noted, with or without metabolic activation.

	The positive controls gave satisfactory responses, confirming the validity of the test system.
CONCLUSION	The notified polymer was not clastogenic to rat lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	Dow (2009)

A.10. Developmental toxicity

TEST SUBSTANCE	Analogue polymer
METHOD	OECD 421 Reproduction/Developmental Toxicity Screening Test
Species/Strain	Rat/Crl:CD(SD)
Route of Administration	Oral – gavage
Exposure Information	Exposure period - female: 39 – 52 days (14 days prior to pairing through to the day prior to sacrifice). Exposure period - male: 46 days (14 days prior to pairing through to the day prior to sacrifice). Dose regimen: daily
Vehicle	Deionized water
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
I	10 per sex	0	0/10
II	10 per sex	60	0/10
III	10 per sex	168	0/10
IV	10 per sex	470	1/10

Mortality and Time to Death

One female receiving the test substance at 470 mg/kg bw/day died on day 22 of gestation. This death was considered treatment related by the study authors and was attributed to the high dosage of test substance (mg/kg bw basis) during late pregnancy. Adverse clinical signs prior to death included decreased motor activity, ptosis, rales and excess salivation.

Effects on Adults

There were test substance-related increases in the number of male and female rats with rales at all dosage levels during the treatment period. This increase was statistically significant compared to controls in males receiving the test substance at 168 and/or 470 mg/kg bw/day and females at 470 mg/kg bw/day only. However, this effect was considered by the study authors to be a secondary effect due to unintentional aspiration of the test substance (considered to be an iatrogenic, not a toxicological effect).

Statistically significant increased incidences of excess salivation were noted in males and females administered the test substance at 470 mg/kg bw/day. In addition, statistically significant increased incidences of ptosis and decreased motor activity were noted in rats of both sexes in the 470 mg/kg bw/day dosage groups. A red or yellow perioral substance was found in males dosed with the test substance at 470 mg/kg bw/day and the incidence of a sparse hair coat was significantly increased in females dosed with the test substance at 470 mg/kg bw/day.

There were numerous other sporadic adverse clinical observations; however, these were considered by the study authors to be unrelated to treatment with the test substance due to a lack of dose dependency, the observation of effects in control animals, or effects in a low percentage of rats in the relevant treatment group.

Mean body weight gain was statistically significantly reduced in males dosed with the test substance at 168

(day 43 onwards) and 470 mg/kg bw/day (day 8 onwards) over the treatment period. At animal sacrifice the mean body weights were 98.9%, 92.9%, and 84.1% of the corresponding control animals in the 60, 168 and 470 mg/kg bw/day groups, respectively. Mean body weight gain was statistically significantly reduced in females dosed with the test substance at 470mg/kg bw/day in the first week but recovered by day 14. The study authors deemed this initial decrease to be treatment related. With the exception of a statistically significant decrease in mean body weight of females treated at 470 mg/kg bw/day during days 18-20 of gestation, which the study authors attributed to a slightly smaller than average litter size, there were no significant changes in mean body weights in females during the gestation and lactation periods.

Absolute and relative food consumption was also statistically significantly decreased in male rats dosed with the test substance at 168 and 470 mg/kg day during the treatment period. This corresponded to the reduction in weight gain and was considered to be treatment related by the study authors. Statistically significant reductions in absolute and relative food consumption were also noted in female rats dosed with the test substance at 470 mg/kg bw/day in the premating period. Statistically significant decreases in the relative food consumption were noted in females of the 168 and 470 mg/kg bw/day dosage groups during the gestation period (days 0-7). While the mean food consumption was noted to have increased during the lactation period in treated animals compared to the controls, there was no dose response relationship, and so was considered non-treatment related by the study authors.

No test substance-related effects on reproductive performance or gestation length were seen in animals of any of the test groups.

There were no test substance-related histopathological effects on reproductive organs and no test substance-related macroscopic findings were noted at the scheduled necropsies for males or females at any dosage level. There were some sporadic histopathological effects, such as testicular atrophy and increased exfoliated spermatogenic cells in 3 males treated at 470 mg/kg bw/day and a mammary gland adenocarcinoma in 1 female dosed with the test substance at 60 mg/kg bw/day. However, the study authors note that these effects are common in the age and strain of the laboratory rat and were not considered to be treatment related. In the case of the male rats, the testicular atrophy did not affect reproductive function.

Effects on Foetus

The mean number of pups born, live litter size and the sex ratio of pups in all dosage groups were similar (not significantly different) to the control group values. There were no treatment-related clinical signs in pups and postnatal survival was unaffected by parental test substance administration.

Mean male and female pup body weights and body weight gains in all dosage groups were unaffected by parental test substance administration.

CONCLUSION

The No Observed Effect Level (NOEL) for maternal/paternal toxicity was established as 60 mg/kg bw/day, based on the adverse clinical effects noted at 168 and 470 mg/kg day of the test substance.

The No Observed (Adverse) Effect Level (NO(A)EL) for reproductive/developmental toxicity was established as ≥470 mg/kg bw/day in this study, based on the absence of adverse effects at the tested doses.

TEST FACILITY CRL (2009)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Ready biodegradability

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test

Inoculum	Activated sludge from municipal sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	DOC and oxygen consumption measured as pressure drop
Remarks - Method	No significant deviations to protocol were reported. Test conditions: pH 7.1 – 7.3, 22 ± 0.5 °C.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation**	*Day*	*% Degradation**
5	11.9	5	64.7
7	16.4	7	68.3
14	37.3	14	72.0
15	42.8	15	74.4
21	61.1	21	74.4
28	67.5	28	72.0

*Based on ThOD

Remarks - Results: The reference substance (sodium benzoate) was degraded >60% by the 14th day, indicating the suitability of the inoculum and test conditions. All validity criteria for the test were satisfied. The test substance did not reach the pass level of 60% degradation within the 10 day window for this test and is therefore classified as not readily biodegradable.

CONCLUSION: The notified polymer is not readily biodegradable

TEST FACILITY: BMG Engineering (2007a)

B.2. Ecotoxicological Investigations

B.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified polymer

METHOD: Quantitative Structure Activity Relationship (QSAR) estimation methods

RESULTS

ECOSAR (v1.00)
Non-ionic surfactant class
LC50 (96 h) mg/L
≥1.46

REMARKS - RESULTS

Surfactant toxicity has been found to depend on carbon chain length (Nabholz et al., 1993) and consequently, QSARs based on chain length have been derived and validated for fish (e.g. ECOSAR (v1.00), non-ionic surfactant class; US EPA, 2011). The 96 hour fish median lethal effect concentrations (LC50) were calculated for representative species of

the notified polymer. The lowest LC50 was 1.46 mg/L and is hence used as a conservative endpoint for fish.

CONCLUSION The notified polymer is toxic to fish

TEST FACILITY US EPA (2011)

B.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static
EEC directive 84/449 C.2 "Acute Toxicity for Daphnia" – Static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None reported
Water Hardness	2.5 mmol/L Mg^{2+} and Ca^{2+}
Analytical Monitoring	None conducted
Remarks - Method	Following a range finding study, a definitive study was conducted according to the guidelines above under static conditions. Test conditions: 20 ± 0.5 °C, pH 7.3 – 7.8, conducted in the dark, dissolved oxygen concentration 2.9 – 6.1 mg/L. In a separate test, test organisms were exposed to a reference toxicant (potassium dichromate). The 48 hour median effect concentration (EC50) was calculated by linear regression analysis of immobilisation versus log concentrations. The 95% confidence interval was calculated using the Student t-test.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	3 × 20	0	4
0.704	n.d.	2 × 20	0	3
1.20	n.d.	2 × 20	0	0
2.03	n.d.	2 × 20	0	0
3.46	n.d.	2 × 20	1	13
5.88	n.d.	2 × 20	7	34
10	n.d.	2 × 20	27	40

EC50	4.22 mg/L at 48 hours (based on nominal concentrations) (95% CI 3.71 – 4.79 mg/L)
NOEC	2.03 mg/L at 48 hours (based on nominal concentrations)
Remarks - Results	All validity criteria were satisfied. No significant deviations from test guidelines were reported.

CONCLUSION The notified polymer is toxic to aquatic invertebrates

TEST FACILITY BMG Engineering (2007b)

B.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Council Regulation No 440/2008 C.3 Algal Inhibition Test.

Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 0.375, 0.75, 1.5, 3, 6 and 12 mg/L Actual: Not determined
Auxiliary Solvent	None reported

Water Hardness	0.18 mmol/L Ca^{2+} and Mg^{2+}
Analytical Monitoring	Not conducted
Remarks - Method	Following a range finding study, a definitive study was conducted according to the guidelines above. Test conditions were: 22 ± 0.5 °C, pH 8.0 ± 0.2, continuous photoperiod with light intensity 8500-9000 lux. The median effect concentrations for biomass (E_yC50) and growth rate (E_rC50) were determined by linear regression analysis of percentage inhibition versus log concentrations. The 95% confidence intervals were calculated using the Student t-test.

RESULTS

Biomass		*Growth*	
E_bC_{50} mg/L at 72 h	*NOEC mg/L*	*E_rC_{50} mg/L at 72 h*	*NOEC mg/L*
0.572	<0.375	1.25	0.375
95% CI 0.35 – 0.76		95% CI 0.87 – 1.66	

Remarks - Results	All validity criteria were satisfied. No significant deviations to protocol were reported.

CONCLUSIONS

Based on the E_rC50, the notified polymer is toxic to algae.

Based on the NOEC, the notified polymer is harmful to algae with long lasting effects.

TEST FACILITY

BMG Engineering (2007c)

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