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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polyquaternium-86

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 the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN 62 008 437 867)
500 Princes Highway NOBLE PARK VIC 3174

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Molecular weight, Polymer constituents, Purity, Impurities, Import volume, Identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting point/freezing point, Boiling point, Hydrolysis as a function of pH, Partition coefficient, Adsorption/desorption, Dissociation constant, Flash point.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Japan

2. IDENTITY OF CHEMICAL

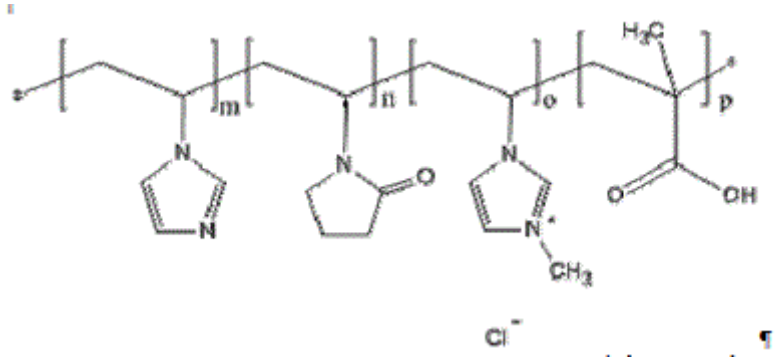
CHEMICAL NAME
1H-Imidazolium, 1-ethenyl-3-methyl-, chloride (1:1), polymer with 1-ethenyl-1H-imidazole, 1-ethenyl-2-pyrrolidinone and 2-methyl-2-propenoic acid

MARKETING NAME(S)
Luvigel Advanced (contains > 95% notified polymer)

CAS NUMBER
935522-29-5

OTHER NAME(S)
INCI name: Polyquaternium-86
Copolymer of vinylpyrrolidone, vinylimidazole, 3-Methyl-1-Vinylimidazolium chloride and methacrylic acid; cross-linked

STRUCTURAL FORMULA



MOLECULAR FORMULA
$(C_6H_9N_2.C_6H_9NO.C_5H_6N_2.C_4H_6O_2.Cl)_x$

MOLECULAR WEIGHT
Mn >10000 Da

ANALYTICAL DATA
Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

ADDITIVES/ADJUVANTS None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES Not expected under normal conditions of use.

DEGRADATION PRODUCTS Not expected under normal conditions of use. Thermal decomposition occurs at temperatures > 300°C (according to MSDS) and may release fumes of carbon monoxide, carbon dioxide and oxides of nitrogen.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: White powder

Property	Value	Data Source/Justification
Glass Transition Temperature	150-155°C	Technical information sheet (BASF, 2009).
Bulk Density	280 kg/m^3	MSDS
Vapour Pressure	Not measured	Notified polymer has a high molecular weight and is not expected to be volatile.
Water Solubility	198-285 mg/g at 20°C	Measured.
Hydrolysis as a Function of pH	Not measured	Expected to be stable, based on the structure.
Partition Coefficient (n-octanol/water)	Not measured	Measurement would be complicated by the surface activity. The partition coefficient of the water soluble fraction is expected to be very low, based on the water solubility.
Adsorption/Desorption	Not measured	Expected to sorb to soil organic matter because of cationic and surface active properties.
Dissociation Constant	Not measured	Expected to be dissociated in the environment because of quaternary ammonium and carboxylic acid functionality.
Particle Size	Inhalable fraction (<100 μm): 100% Respirable fraction (<10 μm): ~82%	Measured.
Flash Point	Not measured	Low vapour pressure solid.
Flammability	Not highly flammable	MSDS.
Autoignition Temperature	480°C	MSDS.
Explosive Properties	Not measured	Does not contain structural groups that imply explosive properties.

DISCUSSION OF PROPERTIES
The solubility tabulated above represents the proportion of the notified polymer that is water soluble (20-30%),

or certain soluble fractions. The more highly cross-linked fraction of the notified polymer is understood to have low water solubility. The notified polymer is observed to swell significantly in contact with water and the swelled material is not water soluble.

The MSDS states that the imported notified polymer powder is a dust explosion hazard and classified as a Class 4.2 (substance liable to spontaneous combustion) dangerous good for transport according to the Australian Dangerous Goods Code (NTC, 2007), but is stable if stored in a dry cool place with container lids kept tightly closed.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as > 95% powder and reformulated into hairstyling products.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 5	< 10	< 10	< 20	< 20

PORT OF ENTRY
Sydney or Melbourne

IDENTITY OF RECIPIENT
BASF Australia Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 20 kg net weight fibreboard boxes and transported by road to a storage warehouse and subsequently to the reformulation site. Following reformulation, the final product containing the notified polymer will be packaged into 100 ml, 150 ml, 200 ml and 250 ml containers before being distributed to end users of the haircare products.

USE
A cationic rheology modifier in hair styling products.

OPERATION DESCRIPTION
Reformulation
Workers will sample and test the imported notified polymer (> 95%) for quality control purposes when it is received at the reformulation site. It will then be transferred using dispensing equipment into large stainless steel mixing vessels. Other ingredients will be added to the mixing vessel and compounded to produce a liquid/gel hair styling product. The concentration of the notified polymer in the finished product will be typically in the range from 0.5 to 2.0%. Following further quality control testing, the product will be pumped via automated, covered filling lines into individual packaging containers. These containers will then be packed into cartons for retail distribution to be purchased by consumers.

End use
The finished hairstyling product containing the notified polymer (0.5-2%) will be in the form of gels, waxes, creams, muds or fudges and will be available for use by hairdressers/hair salon workers. Application of the product will involve the hairdresser rubbing the product between their hands and transferring it to the hair of customers.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hrs/day)*	*Exposure Frequency (hrs/day)*
Transport and Warehouse	2-4	2	20
Laboratory/Quality Assurance	2-4	7	50
Plant Operators – Weighing and Compounding	4-6	8	50
Plant Operators – Filling and Packaging	2-4	2	20
Hairdressing Salon Workers	>1000	1-2	200

EXPOSURE DETAILS

Transport and warehousing

Transport and warehouse workers are not likely to be exposed to the imported powder containing > 95% notified polymer except in the case of an accident or breach of packaging.

Reformulation

Workers may experience dermal, ocular and inhalation exposure to the notified polymer (> 95%) during quality control testing. However, this exposure is expected to be lowered by the wearing of laboratory coats, protective gloves, dust masks and safety glasses. Plant operators involved in powder dispensing may experience dermal, ocular and inhalation exposure to airborne dust of the notified polymer (> 95%). EASE modelling (UK HSE, 1997) of this work environment predicts that atmospheric concentration of dust in a worst case scenario is 4.8-47.5 mg/m^3 for powders consisting of 95% notified polymer. With local ventilation, the estimated atmospheric dust concentration is reduced to 1.9-4.8 mg/m^3. This estimate assumes that no respiratory protection is worn. However, the notifier has indicated that dust protective masks will be worn and powder dispensing equipment used, thus further lowering exposure. Dermal and ocular exposure to the final liquid/gel formulation containing 0.5 to 2.0% notified polymer may occur due to drips or spills when pumps are disconnected and connected during compounding, line filling and packaging. Reformulation workers are expected to wear PPE (gloves, coveralls, safety glasses and safety shoes), which will reduce the likelihood of exposure.

End use

Hairdressers and hair salon workers may experience dermal and accidental ocular exposure to the notified polymer at concentrations of up to 2% during application of hairstyling products to the hair of customers. They are not likely to wear gloves during such application and intermittent, wide-dispersive use with direct handling is expected to occur. According to EASE modelling of this work environment, dermal exposure could result in the range of 1-5mg/cm^2/day of products containing up to 2.0% of the notified polymer.

6.1.2. Public exposure

Members of the public will make dermal contact on their hands and scalp during application of the hairstyling products containing up to 2.0% notified polymer. In most cases exposure is expected to be limited to 5.0 grams of product up to 2 times per day with a retention factor of 0.1 to take into account wash-off during routine hair washing. Assuming a default body weight of 60 kg and dermal absorption of 10% (considering the high molecular weight), the systemic exposure dosage for a product containing 2% notified polymer is estimated to be 0.033 mg/kg bw/day (SCCP, 2006). The hair styling products will be washed off during hair washing and during rinsing, dermal exposure to other parts of the body and accidental ocular exposure may occur.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 > 2000 mg/kg bw, low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution

The potential for absorption of the notified polymer across biological membranes may be limited given the high molecular weight and poor solubility in water. The powdered form of the notified polymer is not readily water-soluble, but is swellable in water.

Airborne dusts of the notified polymer are expected to be readily inhaled given that 100% of particles are less than 100 μm. Around 82% of particles are in the respirable range therefore there is potential for a large proportion of inhaled particles to reach the lower respiratory tract after inhalation and may be retained there. High molecular weight, water-insoluble but water-swellable polymer particles of respirable size are a potential health concern, particularly on the risk of developing lung neoplasms, which has been shown in animal studies on polyacrylate polymer particles (US EPA, 2007). A number of chronic inhalation studies in rats with insoluble nonfibrous particles with low cytotoxicity have also shown the development of chronic pulmonary inflammation, pulmonary fibrosis and lung tumours (Oberdorster, 1995). A possible mode of action is the 'particle overload' effect (Morrow, 1988) in which an excessive volume of particulates in the respiratory system impairs the ability of alveolar macrophages to effectively clear the lungs. Low-toxic particles may not necessarily cause acute effects but have the potential to induce adverse pulmonary changes if high concentrations of particles are inhaled over a long period of time.

Acute toxicity

No sign of systemic toxicity after oral exposure was observed based on a study in rats. The notified polymer is not considered acutely toxic via the oral route.

Irritation and Sensitisation

The notified polymer is considered slightly irritating to the skin of rabbits. Erythema of "well-defined" or "very slight" severity was observed in animals up to 48 hours after skin exposure, but all treated skin sites appeared normal by 72 hours. The observed skin reactions were not sufficient to warrant classification.

In an acute eye irritation test, conjunctival redness and scleral injection ('red eye') was the most prominent reaction in all animals and persisted for 72 hours or 7 days after treatment. Conjunctival chemosis and discharge was observed for up to 48 hours. The notified polymer is considered slightly irritating to the eye of rabbits, though it was not sufficient to warrant classification.

The notified polymer was tested using a mouse local lymph node assay at concentrations up to 30% in EGDME and there was no evidence of skin sensitisation. Based on this result and the high molecular weight, the notified polymer is not expected to be a skin sensitiser.

Mutagenicity

An Ames test on *Salmonella typhimurium* and *E.coli* using the plate incorporation and precincubation test found no significant increase in the number of revertant colonies. Under the conditions of the test, the notified polymer was not mutagenic to bacteria.

Repeat dose toxicity

The notified polymer is not expected to be significantly dermally absorbed due to its high molecular weight, low proportion of low molecular weight species and low water solubility. As such, systemic toxicity following dermal exposure to the notified polymer is expected to be low.

Health hazard classification

Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Reformulation

Exposure and hence the risk of adverse effects is highest during the initial transfer of the notified polymer powder (> 95%) to the blending vessel where workers may inhale airborne particles (even in the presence of local exhaust ventilation). Acute or chronic inhalation exposure to the notified polymer may result in significant lung damage. Thus the inhalation risk to workers handling powders of the notified polymer may be significant. If particle filter masks capable of filtering out particles of respirable size are worn by workers and used and fitted correctly, exposure to the airborne notified polymer and therefore the risk to reformulation workers will be significantly reduced.

The Safe Work Australia Time-Weighted Average (TWA) exposure standard for airborne dusts is 10 mg/m^3, but a recommended exposure limit of 3 mg/m^3 has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for "respirable (insoluble) particulates (not otherwise regulated)".

Dermal and ocular exposure to the notified polymer at concentrations up to 95% may occur. However, given that the level of worker exposure is expected to be mitigated by the use of local exhaust ventilation, dispensing equipment and PPE (gloves, coveralls, safety masks and safety shoes), the risk of irritancy effects is not considered unacceptable. Similar exposure may occur to the reformulated liquid/gel product containing the notified polymer at concentrations of 0.5-2%. At such concentrations, irritancy effects are not likely and exposure is expected to be mitigated by PPE, thus the risk to workers is not considered unacceptable.

End use

Dermal and accidental ocular exposures are the main routes of exposure to the notified polymer (0.5-2%) for hairdressers and salon workers. Whilst the notified polymer is slightly irritating at neat concentrations it is not expected to cause irritancy effects at the proposed use concentrations (up to 2%). In conclusion, the risk to occupational health of hairdressers and hair salon workers is not considered to be unacceptable.

Based on the expected low absorption of the notified polymer, the risk to hairdressers from repeated dermal exposure is not considered unacceptable.

6.3.2. Public health

The public will experience dermal and accidental ocular exposure to the hands and/or scalp to the finished hairstyling products containing up to 2.0% notified polymer at hairdressers or during home use of the products. The exposure and hazard of the notified polymer to members of the public during use of the hair styling products are expected to be similar to that experienced by hairdressers. The notified polymer is not considered to pose an unacceptable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The polymer will be imported into Australia at Melbourne or Sydney, and stored at a contracted warehouse. It will be transported by road to various customers where it will be formulated with other ingredients to produce hair care products (typically hair styling gel). Environmental exposure comes from three main routes. The first route of environmental exposure arises from accidental spills. The notified polymer should be contained physically, collected in an absorbent material, and disposed to secure landfill. The second route of environmental exposure arises from the disposal of import containers with residual notified polymer. It is expected that up to 0.25% of total imported notified polymer will remain in these containers, which will be sent for reconditioning/recycling. The third route of environmental exposure arises from the wastewater produced from cleaning equipment used in the formulation of the notified polymer. This wastewater is disposed to trade waste system and biological processing treatment plant. Once treated, the wastewater is disposed through the sewer according to a permit provided by the water authorities.

RELEASE OF CHEMICAL FROM USE
The end-use products containing the notified polymer are applied to hair as a styling agent. Due to the properties of the polymer, the notified polymer does not bond permanently to the hair and is washed off during routine hair washing. Apart from the minimal quantity remaining in packaging which will be disposed via domestic waste to landfill, the majority of the notified polymer will be released during hair washing to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL
The majority of the notified polymer will ultimately be washed to sewer. A minor proportion will be disposed of with domestic waste to landfill.

7.1.2 Environmental fate

Soluble fractions of the notified polymer may be expected to pass through sewage treatment works as it is not readily biodegradable. In practice, sorption to sludge can be expected because of the cationic and surface active properties of the notified polymer. The high molecular weight, cross-linked fractions can be expected to associate with sludge because of their low water solubility. Residues entering waterways are not expected to bioconcentrate in fish as the large molecular size and cationic properties will preclude passage across biological membranes. Residues disposed of to landfill are expected to slowly degrade *in situ*. For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC can be determined as tabulated below based on the US EPA assumption of 90% removal on passage through a sewage treatment plant of a cationic polymer with a NAMW > 1000 (Boethling and Nabholz 1997).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	< 20000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	< 20000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	< 54.8	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21,374	million
Removal within STP	90%	
Daily effluent production:	4,275	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	< 1.28	µg/L
PEC - Ocean:	< 0.13	µg/L

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	EC50 = 1.3 mg/L	Toxic
Inhibition of Bacterial Respiration	EC50 > 1000 mg/L	Not harmful

The notified polymer is toxic to daphnids, based on the test result tabulated above. The result is based on the mean measured concentrations, which remained fairly constant throughout the exposure period but were only about 60% of the nominal concentrations. This presumably reflects the poor solubility of the cross-linked fractions.

7.2.1 Predicted No-Effect Concentration

The PNEC can be determined as tabulated below by application of a 1000 fold assessment factor to the daphnid toxicity result, as data are only available for one trophic level.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Acute daphnid toxicity	1.3	mg/L
Assessment Factor	1000	
PNEC:	1.3	µg/L

7.3. Environmental risk assessment

The Risk Quotients (Q = PEC/PNEC) are tabulated below.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	< 1.28	1.3	< 0.99
Q - Ocean	< 0.13	1.3	< 0.1

The notified polymer is not considered to pose a risk to the environment at import volumes up to 20 tonnes, as the risk quotients remain below one.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Aquatic toxicity	Acute 2, Chronic 2	Toxic 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 unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable 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 a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure during powder dispensing and reformulation:
  - Local exhaust ventilation where manual handling of the notified polymer in powder form is carried out.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid the generation of airborne dusts
  - For health concerns, the level of atmospheric dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m^3 but a recommended exposure limit of 3 mg/m^3 has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for "respirable (insoluble) particulates (not otherwise regulated)".

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during powder dispensing:
  - Respiratory protection adequate for respirable particulates wherever airborne dusts are likely to be generated.

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken regarding storage of the notified polymer:
  - Keep storage containers tightly closed
  - Store in a cool dry location

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by 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 chemical 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;
- the importation volume exceeds 20 tonnes per annum of notified polymer;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component in hairstyling products, or is likely to change significantly;
- the amount of chemical being introduced has increased from 20 tonnes, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical 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 MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 198-285 mg/g at 20°C

Method Polymer Test Guideline of the Korean National Institute of Environmental Research
Remarks Flask Method. The solubility was determined at nominal concentrations of 0.1 and 1 g/L in demineralised water and buffers (pH 2, 7 and 9). Dissolved concentrations ranged from 20 to 30 mg/L, and from 240 to 325 mg/L, respectively. The values cited above represent the water soluble fractions of the notified polymer.
Test Facility BASF (2008a)

Particle Size 0.14-39.87 μm

Method BASF Particle Measurement (GMP guidelines)

Range (μm)	*Mass (%)*
< 27.5	100
< 13.3	90
< 10.0	82.4
< 5.4	50
< 1.5	10

Remarks Particle size ranges are averaged from four measurements made on the notified polymer.
Test Facility BASF (2008b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 2004/73/EC No. L216 B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Distilled water. The test substance (powder) became a very thick and slightly opaque colourless liquid when prepared in vehicle.
Remarks - Method	Six female animals were administered a single dose of 2000 mg/kg bw by oral gavage.
RESULTS	
LD50	> 2000 mg/kg bw
Signs of Toxicity	No significant sign of toxicity was observed. All animals showed slight piloerection for 4 hours after administration of the test substance and appeared normal at the day 2 observation.
Effects in Organs	No abnormalities were noted.
Remarks - Results	There were no deaths and all animals gained expected bodyweight.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	EVIC France (2008)

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 2004/73/EC No. L216 B.4 Acute Toxicity (Skin Irritation/Corrosion).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Moistened with doubly distilled water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	The moistened test substance had a pH value of 5.

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	1	0.33	0.33	2	< 72 hrs	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	All animals showed well-defined erythema immediately after removal of the patch and persisted in one animal up to 24 hours. Very slight erythema was noted in two animals at the 24-hour observation and in one animal at the 48-hour observation. At 48 hours, very slight erythema was observed in one animal and the remaining two animals appeared normal. All reactions resolved by 72 hours after patch removal.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY BASF (2008c)

B.3. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 2004/73/EC No. L216 B.5 Acute Toxicity (Acute Toxicity - Eye Irritation/Corrosion).

Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 7 days
Remarks - Method The test substance was moistened with water and had a pH value of 5.

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	1	1.67	1.33	2	< 7 days	0
Conjunctiva: chemosis	0.67	0.67	0.33	2	< 48 hrs	0
Conjunctiva: discharge	0	0.67	0	3	< 48 hrs	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results In addition to the conjunctival reactions, injected scleral vessels in a circumscribed area or circular were noted in the animals during the observation, but resolved by 72 hours (one animal) or 7 days (two animals).

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY BASF (2008d)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified polymer

METHOD OECD TG 429 Skin Sensitization - Local Lymph Node Assay
EC Directive 2004/73/EC No. L216 B.42 Skin Sensitization – Local Lymph Node Assay

Species/Strain Mouse/CBA/J
Vehicle Ethylene glycol dimethyl ether (EGDME)
Remarks - Method A concurrent positive control study was not included in this study. Instead, historical positive control data for the substance Alpha-hexylcinnamaldehyde in different vehicles was provided. The test substance was not suitable for dosing in many of the solvents recommended in the OECD test guidelines. The maximum concentration that could be applied in EGDME was 30%. In addition to the validated ^{3}H-thymidine method, the study also evaluated non-radioactive endpoints including cell count and lymph node weight, as well as ear weight.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index* (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	533.9	1.00
3	633.1	1.19
10	792.5	1.48
30	577.8	1.08

* Based on ^{3}H-thymidine incorporation.

Remarks - Results	In addition to the absence of an effect on ^{3}H-thymidine incorporation, t here was no significant dose-dependent effect on lymph node weights and auricular lymph node cell counts compared to the vehicle control. Minimal increases in ear weights were observed at the 10% and 30% concentration groups compared to the control and are considered as an indication of slight ear skin irritation.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.
TEST FACILITY	BASF (2008e)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation test and preincubation test
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Aroclor1254-induced rat liver S9 mix
Concentration Range in Main Test	a) With metabolic activation: 0-5000 µg/plate b) Without metabolic activation: 0-5000 µg/plate
Vehicle	Acetone
Remarks - Method	Acetone was used as the vehicle due to the limited solubility of the test substance in water.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1 – Standard plate test	5000 for TA1537; > 5000 for other strains	≥ 500	Negative
Test 2 – Preincubation test	> 5000	≥ 500	Negative
Present			
Test 1 – Standard plate test	> 5000	≥ 500	Negative
Test 2 – Preincubation test	2500 for TA1537; > 5000 for other strains	≥ 500	Negative

Remarks - Results	There was no increase in the number of revertant colonies either with or without S9 in the standard plate and preincubation test compared to the controls.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY BASF (2008f)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE Notified polymer

METHOD OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum Municipal activated sludge
Exposure Period 28 days
Auxiliary Solvent None
Analytical Monitoring Evolution of carbon dioxide

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
2	-1	2	1
5	-1	5	51
14	-7	14	87
28	-7	28	91

CONCLUSION The notified polymer is not readily biodegradable.

TEST FACILITY BASF (2008g)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.
Species *Daphnia magna*
Exposure Period 48 hours
Auxiliary Solvent None
Analytical Monitoring TOC

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		20	0	0
0.22		20	0	0
0.5		20	0	0

1	0.6	20	0	3
2.2	1.6	20	0	13
5	3.2	20	0	15
10	7.1	20	7	19

LC50 (mean measured concentration)	6.8 mg/L at 24 hours 1.3 mg/L at 48 hours
NOEC (nominal concentration)	0.5 mg/L at 48 hours
CONCLUSION	The notified polymer is toxic to daphnids
TEST FACILITY	BASF (2008h)

C.2.2. Inhibition of microbial activity

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Municipal activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 62.5, 125, 250, 500, 1000 mg/L
Remarks – Method	3,5-Dichlorophenol was used as reference substance.
RESULTS	
IC50	> 1000 mg/L
IC10	370 mg/L
Remarks – Results	The response (IC50 = 7.9 mg/L) to the reference substance was within the prescribed range (5-30 mg/L).
CONCLUSION	The notified polymer is not harmful to the respiration of activated sludge.
TEST FACILITY	BASF (2008i)

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