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

PUBLIC REPORT

Polymer in Sokalan HP 20

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
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TABLE OF CONTENTS

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	4
1. APPLICANT AND NOTIFICATION DETAILS	4
2. IDENTITY OF CHEMICAL.....	5
3. COMPOSITION.....	5
4. PHYSICAL AND CHEMICAL PROPERTIES	5
5. INTRODUCTION AND USE INFORMATION	6
6. HUMAN HEALTH IMPLICATIONS	7
6.1. Exposure Assessment.....	7
6.1.1. Occupational Exposure.....	7
6.1.2. Public Exposure.....	8
6.2. Human Health Effects Assessment	8
6.3. Human Health Risk Characterisation	8
6.3.1. Occupational Health and Safety	8
6.3.2. Public Health	8
7. ENVIRONMENTAL IMPLICATIONS.....	9
7.1. Environmental Exposure & Fate Assessment	9
7.1.1. Environmental Exposure	9
7.1.2. Environmental Fate	9
7.1.3. Predicted Environmental Concentration (PEC).....	10
7.2. Environmental Effects Assessment.....	10
7.2.1. Predicted No-Effect Concentration	11
7.3. Environmental Risk Assessment	11
<u>APPENDIX A: TOXICOLOGICAL INVESTIGATIONS</u>	12
A.1. Acute toxicity – oral	12
A.2 Irritation – skin	12
A.3. Irritation – eye	13
<u>APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS</u>	14
B.1 Environmental Fate.....	14
B.1.1. Biodegradability and Elimination	14
B.2.1. Acute toxicity to aquatic invertebrates.....	14
B.2.2. Inhibition of microbial activity	15
<u>BIBLIOGRAPHY</u>	16

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1554	BASF Australia Ltd	Polymer in Sokalan HP 20	ND*	≤ 200 tonnes per annum	Component of liquid laundry detergents at up to 5%

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

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

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer in Sokalan HP 20 at the formulation sites and during use of liquid laundry detergents containing the notified polymer in Sokalan HP 20:
 - Avoid contact with skin and eyes
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer in Sokalan HP 20:
 - Coveralls
 - Impermeable gloves
 - Safety goggles

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.
- 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:

- Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;
 - the polymer is intended to be used in laundry detergents for hand washing (rather than machine washing);
 - the function or use of the polymer has changed from a component of liquid laundry detergents at up to 5%.

or

- Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of liquid laundry detergents, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 200 tonne 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 MSDS of the product containing 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.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

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

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, degree of purity, polymer constituents, residual

monomers, impurities, additives/adjuvants, import volume, and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: melting/boiling point, density, vapour pressure, water solubility, hydrolysis as a function of pH, partition co-efficient, absorption/desorption, dissociation constant, particle size, flash point, flammability limits, autoignition temperature and explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA, Canada, China, Korea, Philippines

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Sokalan HP 20 (containing the notified polymer at < 80%)

OTHER NAME(S)

Polyethyleneimine, ethoxylated

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

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

DEGRADATION PRODUCTS

No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

Thermal decomposition may release toxic fumes containing products of combustion such as carbon monoxide, carbon dioxide and nitrogen oxides.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: liquid, with mild odour (product)

Property	Value	Data Source/Justification
Freezing Point	Approximately 10°C (101.3 kPa)	Product MSDS (DIN ISO 3016)
Boiling Point	> 100°C (pressure unknown)	Product MSDS
Density	1050-1250 kg/m ³ at 25°C	Product MSDS
Vapour Pressure	2.3 kPa at 20°C	Product MSDS
Water Solubility	Not determined	The notified polymer is expected to be water dispersible at up to 80% in aqueous solution (concentration in imported aqueous concentrates). This is consistent with the structure which contains polar functionalities.
Hydrolysis as a Function of pH	Not determined	The notified polymer does not contain any readily hydrolysable functionality and is therefore expected to be hydrolytically stable.
Partition Coefficient (n-octanol/water)	Not determined	A low partition coefficient is likely on the basis of the water dispersability of

Adsorption/Desorption	Not determined	the notified polymer. The notified polymer is expected to adsorb to soil, sediment and sludge based on its high molecular weight and presence of potentially cationic functional groups.
Dissociation Constant	Not determined	The notified polymer contains functionality that has the potential to become cationic in the environmental pH range (4-9).
Particle Size	Not determined	Imported as dispersion in water.
Flash Point	> 227°C (pressure unknown)	Product MSDS (ASTM D92)
Autoignition Temperature	Not determined	Not expected to self-ignite based on its chemical structure.
Explosive Properties	Not predicted to be explosive	Estimated based on chemical structure.

DISCUSSION OF PROPERTIES

Reactivity

Stable under normal conditions of use.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

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

Sokalan HP 20 containing the notified polymer at < 80% in an aqueous solution will be imported by sea in 1000 L intermediate bulk containers. It will be stored at a contracted warehouse until required for delivery to customers.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	100-200	100-200	100-200	100-200	100-200

PORT OF ENTRY

Sydney

TRANSPORTATION AND PACKAGING

Sokalan HP 20 (containing the notified polymer at < 80%) in 1000 L intermediate bulk containers will be stored at a contracted warehouse until required for delivery to customers for formulation into liquid laundry detergent products. The finished laundry detergent products (containing the notified polymer at ≤ 5%) will be packaged in various retail size plastic packs (typically sizes vary from 475 mL to 3.3 L) and distributed to numerous supermarket outlets within Australia.

USE

Component of liquid laundry detergents for front loader and top loader washing machines to assist with soil removal.

OPERATION DESCRIPTION

At the formulation site, the intermediate bulk container containing the notified polymer < 80% will be connected by hose to a delivery pump and the required amount pumped into a dipper or bucket. The contents of dipper or bucket would then be poured into the blending vessel containing the other ingredients of the liquid laundry detergent. When blended, the batch will be sampled for QC and, once approval is received, formulated laundry products would be packaged for end use and transported by road to retail stores where they will be handled by storage and retail store personnel. The formulated liquid laundry detergent products containing the notified polymer at a concentration of up to 5% will be used by commercial laundry workers and by the public.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and warehousing	1-10	2	< 50
Process workers/operators	1-5	4	100-120
Laboratory technicians/maintenance workers	1-5	4	100-120
Transport and storage workers/retail workers	2000	5-8	200
Commercial laundry workers	5000	5-8	200

EXPOSURE DETAILS

Transport and warehousing workers are not expected to be exposed to the imported product containing the notified polymer at < 80%, as they will be handling closed intermediate bulk containers. Exposure is possible in the event of an accident where the packaging is breached.

Process workers/operators at the formulation site may be exposed to the notified polymer at < 80% during the formulation process. Dermal and ocular exposure to drips and spills may occur during dispensing and charging processes. All process workers/operators are expected to wear eye protection, gloves and coveralls when carrying out these activities.

Laboratory technicians/maintenance workers may be exposed to the notified polymer at < 80% through ocular and dermal routes infrequently during QC testing and maintenance work. They are expected to wear eye protection, gloves and coveralls when carrying out these activities.

Workers involved in packaging the formulated laundry detergents may be exposed to a maximum of 5% of the notified polymer.

Transport and storage workers of the end use products and retail workers may be exposed to the formulated laundry detergents containing the notified polymer at < 5% in the event of an accident if the packaging is breached.

Commercial laundry workers may be exposed to a maximum of 5% of notified polymer when handling the containers and adding the detergent to the washing machine. The main route of exposure will be dermal. Some ocular exposure is also possible. Precautions to reduce worker exposure in commercial laundries are likely to be based on the other ingredients of the laundry detergents.

6.1.2. Public Exposure

Incidental exposure of the public may occur during handling and use of liquid laundry detergent products containing up to 5% of notified polymer. Incidental dermal/ocular exposure may result from spills and splashes of laundry products. It is expected that such splashes would be washed from the skin. The public may also come into incidental contact with wash water containing the laundry detergent products at low dilutions.

Accidental ingestion could occur if children ingested the product containing the notified polymer.

Significant exposure to the notified polymer from washed clothing and linen is not expected to occur as the polymer is expected to be rinsed from the washed articles prior to drying.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on Lutensol FP 620 (approximately 80% notified polymer in water) are summarised in the table below. Details of these studies can be found in Appendix A.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating

Toxicokinetics and distribution

Based on the high molecular weight (NAMW > 1000 Da) and a small percentage of low molecular weight species < 1000 Da (< 2%) and < 500 Da (< 1%), dermal absorption is expected to be low, limiting the potential for systemic exposure.

Acute toxicity

The notified polymer is expected to be of low acute toxicity via the oral route based on a study to OECD guidelines (refer Appendix A.1). No acute dermal or inhalation toxicity data was provided.

Irritation

The notified polymer is expected to be slightly irritating to the skin and eyes, based on studies carried out to OECD guidelines (refer Appendices A.2 and A.3).

The notified polymer contains a functional group of concern for sensitisation, with a functional group equivalent weight (FGEW) < 5000 Da.

Health hazard classification

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

However, based on a structural alert, the potential for skin sensitisation cannot be ruled out.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer is expected to be slightly irritating to the skin and eyes and the potential for skin sensitisation cannot be ruled out. Systemic effects are not expected due to the expected low dermal absorption of the notified polymer.

Workers most at risk are process workers handling the product Sokalan HP 20 containing the notified polymer at a concentration of < 80%, particularly when transferring it to the blending vessels. This risk should be minimised through the stated use of PPE and local exhaust ventilation.

The risk to all other workers including commercial laundry workers is expected to be lower, given they will only handle products containing the notified polymer at 5% or less.

Overall, the risk to workers of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Given the public will only have incidental dermal/ocular exposure to laundry washing products containing the notified polymer and its concentration in the products will be 5% or less, the risk of irritant effects from the notified polymer is considered to be low, even considering that the public are unlikely to wear PPE. The risk of skin sensitisation cannot be ruled out, as there is a structural alert and no test data is available for this endpoint. The risk would be lessened by the incidental nature of exposure for this use, the low levels of low molecular weight species, and the relatively low concentration of the notified polymer in laundry washing products.

Overall, the risk to public health of the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer is not manufactured in Australia; therefore, there is no release from this activity. Environmental release during importation, transport and distribution may occur as a result of accidental spills. In the event of a spill, the notified polymer is expected to be contained and collected with an inert absorbent material and disposed of in accordance with local regulations.

The notified polymer is reformulated at one site in Australia. Release of the notified polymer may occur from disposal of import container residues (estimated at up to 1% of import volume), equipment washings and spills (a further 1%) during reformulation activities. Import containers containing residues are expected to be either disposed of to landfill or reconditioned. Equipment cleaning effluent is expected to be treated on site where the majority of the notified polymer is likely to partition to solids and subsequently be disposed of to landfill. Spills and clean-up material are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer is expected to be released to sewer in domestic situations across Australia as a result of its use in laundry products.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues in end-use containers are estimated to contain 1% of the import volume and are expected to be disposed of to landfill.

7.1.2. Environmental Fate

Following its use in Australia, the majority of the notified polymer will enter the sewer system. Hydrolysis is not expected due to its structure. The notified polymer is not readily biodegradable but is inherently biodegradable (see Appendix B). Based on its high molecular weight and potential cationic functional groups, 90% is predicted to be removed during sewage treatment plant (STP) processes through partitioning to solids (Boethling and Nabholz, 1997). In the case of release to surface waters, the notified polymer is expected to adsorb to particulates and slowly degrade. The notified polymer is not expected to be mobile when disposed of to landfill, or applied to agricultural soils in biosolids or effluent, as it is expected to strongly adsorb to soils based on its high molecular weight and presence of potentially cationic functional groups. The notified polymer is not expected to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate. The notified polymer is expected to slowly degrade to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The following Predicted Environmental Concentrations (PEC) has been calculated assuming that all of the imported quantity of notified polymer will be released to sewer. Of this, 90% is predicted to be removed by sewage treatment plant (STP) processes (Boethling and Nabholz, 1997) before discharge to surface waters on a nation wide basis.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	200,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	200,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	547.95	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	90%	Mitigation
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	12.95	µg/L
PEC - Ocean:	1.29	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 1165.236 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m³ and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 7.768 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 38.84 mg/kg and 77.68 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 12.947 µg/L may potentially result in a soil concentration of approximately 86.31 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 0.43 mg/kg and 0.86 mg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on Lutensol FP 620 (approximately 80% notified polymer in water) are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	Result	Assessment Conclusion
Daphnia Toxicity	EC50 (48 h) > 100 mg/L	Not harmful to aquatic invertebrates
Inhibition of Bacterial Respiration	IC50 (0.5 h) > 1000mg/L	Not inhibitory to microbial respiration

On the basis of the available test data, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified polymer is not harmful to aquatic invertebrates, and would not be formally classified.

Cationic polymers are of concern to all trophic levels in the aquatic environment. Therefore, additional ecotoxicological endpoints for the notified polymer were calculated based on SAR equations assuming a worst case cation charge density for the polymer (Boethling and Nabholz, 1997). The endpoints are summarised in the table below and have been modified by mitigation factors to account for the anticipated binding of the polymer with organic carbon in surface waters.

Endpoint	Result	Assessment Conclusion
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Fish Toxicity	LC50 (96 h) = 63.5 mg/L	Harmful to fish
Daphnia Toxicity	EC50 (48 h) = 281.8 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 30.2 mg/L	Harmful to alga

The notified polymer is potentially harmful to aquatic organisms in environmental waters with typical levels of total organic carbon. The QSAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The estimated hazard data for the notified polymer indicates that, after allowing for the mitigating effects of organic carbon in surface waters, the most sensitive ecotoxicological endpoint is for algae. The endpoint for algae was therefore selected for the calculation of the PNEC below. Given that the measured endpoints are not inconsistent with the calculated endpoints an assessment factor of 100 was considered appropriate in this case and was applied to account for chronic ecotoxicity and extrapolation from lab to field.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga).	30.24	mg/L
Assessment Factor	100	
PNEC:	302.40	µg/L

7.3. Environmental Risk Assessment

The risk quotients ($Q = \text{PEC}/\text{PNEC}$) are calculated below:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	12.95	302.4	0.043
Q - Ocean:	1.29	302.4	0.004

The notified polymer is used in laundry products and the majority of the import volume is expected to be disposed of to sewer. The majority of the notified polymer is expected to partition to solids during STP processes and be disposed of to landfill, or applied to agricultural soils, where it is expected to slowly degrade. Cationic polymers are of concern to aquatic organisms. However, toxicity is mitigated through adsorption to solids, such as organic material in natural waters, and the notified polymer is not expected to reach ecotoxicologically significant concentrations due to efficient removal during sewage treatment processes. Based on the PEC/PNEC and assessed use pattern, 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	Lutensol FP 620 (approximately 80% notified polymer in water)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar
Vehicle	Distilled water
Remarks – Method	No deviations from the protocol.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose (mg/kg bw)</i>	<i>Mortality</i>
1	3 M	2000	0
2	3 F	2000	0

LD50 > 2000 mg/kg bw

Signs of Toxicity For male animals, no signs of toxicity were observed during clinical examination. For female animals, sign of toxicity noted in the 2000 mg/kg administration group was piloerection and was observed only at hour 4 after administration.

Effects in Organs No macroscopic pathologic abnormalities were noted in the animals examined at termination of the study.

Remarks – Results The mean body weights of the administration groups increased throughout the study period.

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

TEST FACILITY BASF (2002a)

A.2 Irritation – skin

TEST SUBSTANCE Lutensol FP 620 (approximately 80% notified polymer in water)

METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	2 F, 1 M
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks – Method	No deviations from the protocol.

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0.3	0	0	1	< 48 h	0
<i>Oedema</i>	0	0	0	0	-	0

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

Remarks – Results Slight erythema (grade 1) was observed in all animals 1 hour after removal of patch and persisted in 1 animal up to 24 hours after removal of the patch. No other cutaneous reactions were observed during the study. The cutaneous reactions were reversible in all animals within 48 hours after

removal of the patch.

CONCLUSION The test substance is slightly irritating to the skin.

TEST FACILITY BASF (2002b)

A.3. Irritation – eye

TEST SUBSTANCE Lutensol FP 620 (approximately 80% notified polymer in water)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain Rabbit/New Zealand White
Number of Animals 2 F, 1 M
Observation Period 72 hours
Remarks – Method No deviations from the protocol.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	<i>Animal No.</i>					
	1	2	3			
<i>Conjunctiva: redness</i>	0.7	1	1	2	< 72 h	0
<i>Conjunctiva: chemosis</i>	0	0	0	2	< 24 h	0
<i>Conjunctiva: discharge</i>	0	0	0	2	< 24 h	0
<i>Corneal opacity</i>	0	0	0	0	-	0
<i>Iridial inflammation</i>	0	0	0	0	-	0

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

Remarks – Results Slight or moderate conjunctival redness (grade 1 or 2), slight or moderate conjunctival chemosis (grade 1 or 2) and moderate discharge (grade 2) were observed 1 hour after application in all animals.
24 hours after application moderate conjunctival redness was observed in all animals and decreased in 2 animals to slight conjunctival redness after 48 hours.
Moreover, injected scleral vessels in a circumscribed area were observed at 24 and 48 hours in 1 animal.
The ocular reactions were reversible in all animals within 72 hours after the application.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY BASF (2002c)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1 Environmental Fate

B.1.1. Biodegradability and Elimination

TEST SUBSTANCE	Lutensol FP 620 (approximately 80% notified polymer in water)
METHOD	ISO Standard 9439 Annex D – Water Quality – Evaluation in an aqueous medium of the ultimate aerobic biodegradability of organic compounds
Inoculum	Activated sludge, domestic
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	CO ₂ /DOC
Remarks - Method	Nominal content of the test substance was 93 mg/L, equivalent to 40 mg/L total organic carbon content.

RESULTS

Day	Notified polymer (40 mg/L TOC)		Aniline (40 mg/L)	
	% Degradation CO ₂ /ThCO ₂	% Elimination DOC	% Degradation CO ₂ /ThCO ₂	% Elimination DOC
1	0	3		
3	0	8		
5	5	21		
7	11	23		
14	19	25	89	95
21	22	23		
28	26	25		

Remarks - Results

The validity criteria were met for the reference substance. Biodegradation degree after 28 days was 26% (by CO₂/ThCO₂). Elimination degree after 28 days was 25% (by DOC). Degradation in the range 20-60% by CO₂/ThCO₂ was considered to be moderately or partially biodegradable. Degradation in the range 20-60% by DOC was considered to be moderately or partially eliminable from water.

It was stated that ready biodegradability may be concluded from the test results. However, the test substance did not meet the readily biodegradable criteria of greater than 60% of the theoretical value within the 10 days of achieving 10%.

CONCLUSION

The test substance is not readily biodegradable. The test substance is inherently biodegradable.

TEST FACILITY

BASF (2002d)

B.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Lutensol FP 620 (approximately 80% notified polymer in water)
METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test – Static. EC Directive 92/69/EEC C.2 Acute Toxicity for <i>Daphnia</i> – Static.
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg CaCO ₃ /L (M4 media)
Analytical Monitoring	Potentiographic titration with surfactant sensitive electrode
Remarks - Method	There were no significant deviations from the test protocol.

RESULTS

<i>Concentration mg/L</i>		<i>Number of D. magna</i>	<i>Number Immobilised</i>	
<i>Nominal</i>	<i>Actual</i>		<i>24 h</i>	<i>48 h</i>
Control	< 2	20	0	0
12.5	12.2	20	0	0
25	Not determined	20	0	0
50	Not determined	20	0	0
100	98	20	0	0

EC50 > 100 mg/L at 24 hours and 48 hours

NOEC > 100 mg/L at 48 hours

Remarks - Results The validation criteria were met. Measured concentrations are the geometric mean of analysis at 0 and 48 h. Nominal concentrations are used to report the EC50 and NOEC as the measured concentration is within 80% of the nominal. Statistical analysis was not conducted due to absence of observed effects.

CONCLUSION The test substance is not harmful to aquatic invertebrates.

TEST FACILITY BASF (2002e)

B.2.2. Inhibition of microbial activity

TEST SUBSTANCE Lutensol FP 620 (approximately 80% notified polymer in water)

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum Activated sludge, domestic, non-adapted

Exposure Period 30 minutes

Concentration Range Nominal: 1000 mg/L

Remarks – Method Limit test. The nominal exposure period under the test protocol is 3 hours although the test protocol allows for a 30 minute exposure period if the test substance is rapidly degraded. Justification for using a 30 minute exposure period was not provided. There were no other significant deviations from the test protocol.

RESULTS

IC50 (30 minutes) > 1000 mg/L

IC20 (30 minutes) > 1000 mg/L

Remarks – Results The validation criteria were met. There was a 12% reduction in oxygen consumption rates at a concentration of 1000 mg/L of the notified polymer. The IC20 was regarded as the limit value for possible toxic effects in wastewater treatment plants. Therefore, the test substance is not expected to disturb biodegradation processes of activated sludge in adapted wastewater treatment plants.

CONCLUSION Not expected to inhibit microbial respiration

TEST FACILITY BASF (2002f)

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