File No: LTD/2045

September 2018

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Ebecryl 4266

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANTS	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2045	Allnex Resins Australia Pty Ltd Axalta Coating Systems Australia Pty Ltd	Polymer in Ebecryl 4266	Yes	< 1 tonne per annum	Component of industrial coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

Hazard classification	*Hazard statement*
Serious eye damage/eye irritation (Category 2A)	H319 – Causes serious eye irritation

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

Hazard classification	*Hazard statement*
Chronic toxicity (Category 2)	H411 – Toxic to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  – Serious eye damage/eye irritation (Category 2A); H319 – Causes serious eye irritation

  The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified polymer present.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer:
  - Enclosed and automated reformulation processes where possible with local exhaust ventilation
  - Spray booths where spray applications occur

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

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Protective clothing
  - Impervious gloves
  - Eye protection
  - Respiratory protection (when spray painting)

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

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

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1,000 g/mol;

or

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

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

Safety Data Sheet
The SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified polymer were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANTS
Allnex Resins Australia Pty Ltd (ABN: 24 160 397 768)
49-61 Stephen Road
BOTANY NSW 2019

Axalta Coating Systems Australia Pty Ltd (ABN: 53 158 497 655)
15-23 Melbourne Road
RIVERSTONE NSW 2765

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 g/mol

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, polymer constituents, purity, 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 for all physicochemical properties except for density, partition coefficient and flash point.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
Canada, New Zealand, Taiwan and USA

2. IDENTITY OF CHEMICAL

MARKETING NAME
Ebecryl 4266 (product containing the notified polymer at ≤ 65% concentration)

OTHER NAME(S)
Roskydal UA VP LS 2266 (product containing the notified polymer at ≤ 65% concentration)

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) is > 1,000 g/mol

ANALYTICAL DATA
Reference GPC and FTIR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 97%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point	Not determined	Liquid at room temperature*
Boiling Point	> 100 °C	SDS*
Density	1,150 kg/m^3 at 23 °C	Measured*
Vapour Pressure	< 11 kPa at 50 °C	SDS*
Water Solubility	HPLC method was not sensitive enough to measure water solubility	Expected to be low
Hydrolysis as a Function of pH	HPLC method was not sensitive enough to measure hydrolysis	Contains hydrolysable functionalities but significant hydrolysis is not expected based on predicted low water solubility
Partition Coefficient (n-octanol/water)	log P_{ow} = 2.80-3.81	Measured*
Adsorption/Desorption	Not determined	Expected to have low mobility in soil based on predicted low water solubility
Dissociation Constant	Not determined	Contains potential cationic functionality but dissociation is expected to be limited based on predicted low water solubility
Flash Point	> 100 °C	SDS*
Flammability	Not determined	Not expected to be flammable
Autoignition Temperature	Not determined	Not expected to undergo autoignition under normal conditions of use
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

*For the product containing the notified polymer at ≤ 65% concentration

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties refer to Appendix A.

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

Physical hazard classification
Based on the limited submitted physicochemical data provided, the notified polymer cannot be recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia as a component of finished coatings at ≤ 25% concentration. In the future, the neat notified polymer may be imported for reformulation into finished coatings within Australia.

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

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

PORT OF ENTRY
Sydney, Melbourne and Brisbane

TRANSPORTATION AND PACKAGING
The notified polymer will be imported as a component of finished coatings at ≤ 25% concentration in 400 mL aerosol cans or in 1 L steel cans, or in the neat form in 20 L pails, 200 L drums or 1 tonne intermediate bulk containers (IBC). Within Australia the finished coatings containing the notified polymer will be transported by road or rail to the warehouse for storage and later distributed to retailers by road or rail for sale to industrial customers. The neat notified polymer will be transported by road to the warehouse for storage and later distributed to the industrial customers for reformulation by road.

USE
The notified polymer will be used as a component of coatings at ≤ 25% concentration and will be used by professional users in the transportation and industrial coatings industry (e.g. equipment, automotive and aviation refinish).

OPERATION DESCRIPTION
The notified polymer will be imported into Australia as a component of finished coatings at ≤ 25% concentration. In the future, the neat notified polymer may be imported for reformulation into coatings within Australia.

Reformulation of the neat notified polymer into finished coatings may involve both automated and manual transfer steps. Typically, reformulation processes may incorporate blending operations that are highly automated and occur in a fully enclosed/contained environment, followed by sampling of the finished products for quality control testing. The finished coatings containing the notified polymer at ≤ 25% concentration will be filled (automated process) into cans of various sizes.

The finished coatings containing the notified polymer at ≤ 25% concentration will only be used by professionals in industrial settings. Application is expected to be conducted in spray booths or in an adequately ventilated area by spray or brush.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	1-2	20
Reformulation	8	100
End users (application of coatings)	8	300

EXPOSURE DETAILS
Transport and storage
Transport and storage workers may come into contact with the notified polymer in its neat form or as a component of finished coatings at ≤ 25% concentration, only in the unlikely event of an accidental rupture of the packaging.

Reformulation processes
Dermal and ocular exposure to the notified polymer at ≤ 100% concentration may occur when connecting or disconnecting transfer hoses, cleaning or maintaining equipment and testing for quality control. Inhalation exposure to the notified polymer may also occur if aerosols are formed. Exposure should be minimised through the use of enclosed and automated systems, local exhaust ventilation and personal protective equipment (PPE: goggles, impervious gloves, coveralls and respirators) as stated by the notifier.

End-use
Dermal, ocular and inhalation exposure to the notified polymer at ≤ 25% concentration may occur during application of the finished coatings. Coating application will be primarily by spray, but potentially with brush and roller. As stated by the notifier, the potential for exposure should be minimised through the use of PPE (goggles, impervious gloves, coveralls) by workers, including the use of respiratory protection during spray

application. Inhalation exposure should be further mitigated through the use of exhaust ventilation and spray booths, where possible. After application and once dried, the notified polymer will be cured into an inert solid matrix and will not be available for exposure.

6.1.2. Public Exposure

Finished coatings containing the notified polymer at ≤ 25% concentration are intended for industrial use only and will not be sold to the general public. The public may come into dermal contact with substrates on which the coatings have been applied. After application and once dried, the notified polymer will be cured into an inert solid matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on a product containing the notified polymer at 50-60% concentration (Ebecryl 4266) are summarised in the following table. For full details of the studies that were not assessed by Canada, refer to Appendix B. It is assumed that all toxicity observed is attributable to the notified polymer.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation –non-adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics

Based on the high molecular weight of the notified polymer, absorption across biological membranes is expected to be limited. However the notified polymer contains a high percentage of low molecular weight species (< 1,000 g/mol), therefore absorption cannot be ruled out.

Acute toxicity

The product containing the notified polymer at 50-60% concentration is of low acute oral toxicity based on a study conducted in rats.

No studies were submitted for acute dermal toxicity. No signs of systemic toxicity were observed in a dermal irritation study or in a guinea pig non-adjuvant skin sensitisation study on a product containing the notified polymer at 50-60% concentration.

No studies were submitted for acute inhalation toxicity.

Irritation and sensitisation

The product containing the notified polymer at 50-60% concentration is non-irritating to skin of rabbits.

The product containing the notified polymer at 50-60% concentration is irritating to eyes based on a study conducted in rabbits. Irritation effects included conjunctival chemosis (maximum grade 3, persisted up to 5 days), conjunctival reddening (max. grade 1, persisted up to day 6), corneal opacity (maximum grade 1, persisted up to day 18) and iridial inflammation (maximum grade 1, persisted up to 12 days).

The product containing the notified polymer at 50-60% concentration was determined not to be a skin sensitiser in a guinea pig non-adjuvant skin sensitisation test.

Repeated dose toxicity

No studies were submitted for repeated dose toxicity of the notified polymer. Systemic effects cannot be ruled out given the high percentage of low molecular weight species (< 1,000 g/mol).

Mutagenicity

The product containing the notified polymer at 50-60% concentration tested negative in a bacterial reverse mutation assay.

Health hazard classification

Based on the available information on a product containing the notified polymer at 50-60% concentration and assuming all toxicity is attributable to the notified polymer, the notified polymer is recommended for hazard

classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Serious eye damage/eye irritation (Category 2A)	H319 – Causes serious eye irritation

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the toxicological information provided, the notified polymer may present as an eye irritant. No repeat dose toxicity data of the notified polymer was provided. Given the high percentage of low molecular weight species (< 1,000 g/mol), systemic effects cannot be ruled out.

Reformulation

During reformulation, workers may be at risk of systemic or eye irritation effects when handling the notified polymer at ≤ 100% concentration. This risk should be reduced through the expected use of PPE (coveralls, impervious gloves and safety glasses) and engineering controls (enclosed, automated processes and mechanical ventilation) which should minimise worker exposure.

End-use

During end use, workers may at risk of systemic or eye irritation effects when handling finished coatings containing the notified polymer at ≤ 25% concentration. This risk should be reduced through the expected use of PPE (coveralls, impervious gloves and safety glasses), including the use of respiratory protection during spray application, which should minimise exposure. Inhalation exposure should be further mitigated through the use of exhaust ventilation and spray booths, where possible. After application and once dried, the notified polymer will be cured into an inert solid matrix and will not be available for exposure

Therefore, provided that PPE is worn by workers and engineering controls are in place to limit exposure, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

End use coatings containing the notified polymer at ≤ 25% concentration will be used in industrial settings only and will not be made available to the public. The public may come into contact with articles containing the notified polymer. However, once the notified polymer is cured and dried, it will be bound within a polymer matrix and will not be available for exposure. Therefore, when used in the proposed manner, 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

The notified polymer will be imported into Australia as a component of finished industrial coatings at ≤ 25% concentration. In the future, the neat notified polymer may be imported for local reformulation into finished coatings. The reformulation processes typically involve blending operations that are highly automated and occur in a fully enclosed environment, followed by automated filling of the finished coatings into end-use containers. Liquid waste from reformulation equipment cleaning is expected to be collected and disposed of by an approved waste management facility. Release of the notified polymer in the event of accidental spills or leaks during reformulation, storage and transport is expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The coatings containing the notified polymer will be used by professional users in the transportation and industrial coatings industry. Application is expected to be conducted in spray booths or in an adequately ventilated area by spray or brush according to best practices. The main release of the notified polymer is likely from overspray during use. The overspray is expected to be collected by spray booth filters or other standard engineering controls before disposal to landfill. Solvent waste from application equipment cleaning is expected

to be collected and disposed of by an approved waste management facility, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL
Most of the notified polymer is expected to share the fate of the articles to which it has been applied, either subjected to metal reclamation processes or being disposed of to landfill at the end of their useful lives. The notifier estimated that up to 0.5 % of the import volume of the notified polymer could remain as residues in empty containers, which is expected to be disposed of by approved waste management facilities in accordance with local government regulations.

7.1.2. Environmental Fate
A biodegradation test conducted on a product containing the notified polymer at 50-60% concentration shows that it is not readily biodegradable (7% degradation in 28 days). Although the notified polymer contains high percentage of low molecular weight constituents, it is not expected to be bioaccumulative based on the partition coefficient for a product containing the notified polymer at 50-60% concentration (log P_{ow} = 2.80 - 3.81). As a result of its use pattern, most of the notified polymer is expected to share the fate of the articles to which it has been applied, either subjected to metal reclamation processes or being disposed of to landfill at the end of their useful lives. During metal reclamation processes, the notified polymer will thermally decompose to form water vapour and oxides of carbon and nitrogen. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile. Therefore, release of the notified polymer to the aquatic environment is expected to be minimal. In landfill the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)
The predicted environmental concentration (PEC) has not been calculated as release of the notified polymer to the aquatic environment will be limited based on its reported use pattern as a component of industrial coatings.

7.2. Environmental Effects Assessment
The results from ecotoxicological investigations conducted on a product containing the notified polymer at 50-60% concentration are summarised in the table below. For full details of the studies that were not assessed by Canada, refer to Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96h LC50 = 5.62 mgWAF*/L	Toxic to fish
Daphnia Toxicity	48h EC50 > 100 mgWAF*/L	Not harmful to aquatic invertebrates
Algal Toxicity	72h EC50 = 12 mgWAF*/L	Harmful to alga
Inhibition of Bacterial Respiration	0.5h IC50 > 10,000 mg/L	Not inhibitory to microbial activity at STPs

*WAF: Water Accommodated Fraction

The tested product contains 50-60% of the notified polymer and it is assumed that all the toxicity is attributable to the notified polymer. On this basis the notified polymer is expected to have acute toxicity of 2.8-3.4 mg/L, to fish and 6.0-7.2 mg/L to algae and thus, the notified polymer is regarded as toxic to fish and alga. Therefore, the notified polymer is formally classified as “Acute Category 2; Toxic to aquatic life” under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Based on the acute toxicity and lack of readily biodegradability, the notified polymer is formally classified as “Chronic Category 2; Toxic to aquatic life with long lasting effects” under the GHS (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration
The most sensitive endpoint from the above ecotoxicity tests on the notified polymer is 96 h EC50 for fish, and this was selected for the calculation of the predicted no-effect concentration (PNEC). An assessment factor of 100 was used as acute endpoints for three trophic levels are available as a general indication of potential toxicity. Given the tested product containing approximately 50% of the notified polymer and assuming that all toxicity is attributable to the notified polymer, the PNEC is calculated as follows.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
96h EC50 for fish	2.8	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	

PNEC:	28 µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) for the aquatic compartment has not been calculated as release of the notified polymer to the aquatic environment will be minimal based on its reported use pattern. Therefore, on the basis of the reported use pattern as a component of industrial coatings, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Density 1,150 kg/m^3 at 23°C

Method	OECD TG 109 Density of Liquids and Solids EC Council Regulation No 440/2008 A.3 Relative Density
Remarks	In-house method. Determined using a pycnometer.
Test Facility	Allnex (2017)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin

TEST SUBSTANCE	Product containing the notified polymer at 50-60% concentration
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion
Species/Strain	Rabbit (strain details not provided)
Number of Animals	3 M
Vehicle	Moistened with water
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	There were no deaths or signs of systemic toxicity. No erythema or oedema was observed.
CONCLUSION	The test substance is non-irritating to the skin.
TEST FACILITY	LPT (1998a)

B.2. Irritation – eye

TEST SUBSTANCE	Product containing the notified polymer at 50-60% concentration
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion
Species/Strain	Rabbit (details of strain used not provided)
Number of Animals	3 M
Observation Period	19 days
Remarks - Method	Fluorescein test was performed at 24 hours, 7 days and 14 days. 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			
Conjunctiva: redness	1	1	1	1	< 7 days	0
Conjunctiva: chemosis	2.3	1	3	3	< 6 days	0
Conjunctiva: discharge						
Corneal opacity	1	1	1	1	< 19 days	0
Iridial inflammation	1	0.7	1	1	< 13 days	0

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

Remarks - Results	Corneal opacity (grade 1) was observed in all 3 animals at 24 hours to 4 days observations. The symptom persists up to 6 days in one animal and up to 18 days in another animal. In the fluorescein test (performed after 24 hours), 75%t (in two animals) and 100% (in one animal) corneal staining was observed. Fluorescence test performed after 7 days and 14 days, the animal than had 100% staining at 24 hour fluorescence testing showed 50% and 25% corneal staining respectively. All animals exposed to the test substance showed irritation in iris (grade 1) at 24 and 48 hour observations and the symptom persists in one animal at the day 6 observation and in other animal at the day 12 observation. Conjunctival redness (grade 1) was observed in all animals at 1 to 72 hour observations and it persisted in one animal at day 4 observation and in

another animal at day 6 observation.

Chemosis (grade 1 in two animals and grade 2 in one animal) was observed at 1 hour observation and persisted up to day 5 observation in one animal. Two and one animals showed grade 3 and grade 2 chemosis respectively at the 24 hour observation and the symptom was resolved at the day 5 observation.

CONCLUSION The test substance is irritating to the eye.

TEST FACILITY LPT (1998b)

B.3. Skin sensitisation – Buehler test

TEST SUBSTANCE Product containing the notified polymer at 50-60% concentration

METHOD OECD TG 406 Skin Sensitisation – Buehler test

Species/Strain Guinea pig/SPF Hsd Poc:DH

PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 25%

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 10

Vehicle Polyethylene glycol 400

Positive control Induction: α-hexylcinnamaldehyde (conducted in parallel) and for maximisation: 2–mercaptobenzothiazole (conducted in parallel).

INDUCTION PHASE Induction Concentration:
topical: 50% (three inductions at 7 days intervals)

Signs of Irritation One animal showed slight localised redness (grade 1) 30 hours after third induction. No signs of irritation were observed in other 19 test animals.

CHALLENGE PHASE

1st challenge topical: 25%

2nd challenge not conducted

Remarks - Method A dose range-finding study for inductions was conducted using 100% of the test substance. One animal treated at 50% and two animals treated at 100% showed skin reaction at 30 hour observation. Based on the results the highest concentration selected for the inductions was 50%. A dose range-finding study for challenge was conducted during inductions using 25% of the test substance and as no skin reactions were observed up to 25%, the highest concentration selected for challenge was 25%.

Observations for skin reactions were made 30 hour and 54 hour after challenge.

No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		30 h	*54 h*	*24 h*	*48 h*
Test Group					
	25%	0/20	0/20	Not conducted	Not conducted
Control Group					
	25%	0/10	0/10	Not conducted	Not conducted

Remarks - Results No skin reactions were observed in test and control animals at challenge.

Body weight increase was observed for treated animals.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the

test substance under the conditions of the test.

TEST FACILITY Bayer (1998a)

B.4. Genotoxicity – bacteria

TEST SUBSTANCE Product containing the notified polymer at 50-60% concentration

METHOD OECD TG 471 Bacterial Reverse Mutation Test
Plate incorporation method (Test 1)/Pre-incubation method (Test 2)

Species/Strain *Salmonella typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System S9 mix from Aroclor 1254 induced rat liver
Concentration Range in Main Test a) With metabolic activation: 16, 50, 158, 500, 1,581 and 5,000 µg/plate
b) Without metabolic activation: 16, 50, 158, 500, 1,581 and 5,000 µg/plate
Vehicle Dimethyl sulfoxide
Remarks - Method A preliminary test at a concentration range of 16 to 5,000 µg/plate (with and without metabolic activation) was conducted on TA98, TA100, TA102, TA1535 and TA1537. This was used as Test 1.

Negative control: distilled water
Positive control: With metabolic activation: 2-aminoanthracene (all strains)
Without metabolic activation: sodium azide (TA1535 and TA100), nitrofurantoin (TA100), 4-nitro-1,2-phenylene diamine (TA1537 and TA98) and cumene hydroperoxide (TA102)

No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 1,581	≥ 1,581	≥ 1,581	Negative
Test 2		≥ 1,581	≥ 1,581	Negative
Present				
Test 1	≥ 1,581	≥ 1,581	≥ 1,581	Negative
Test 2		≥ 1,581	≥ 1,581	Negative

Remarks - Results Cytotoxicity was observed on TA1535 and TA100 strains at a concentration of ≥ 1,581 µg/plate.

No statistically significant increase in revertant colony numbers of any of the five tester strains was observed following treatment with the test substance at any dose level, in the presence or absence of metabolic activation. There were also no dose dependent increases in mutation rates.

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

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

TEST FACILITY Bayer (1998b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Inhibition of microbial activity

TEST SUBSTANCE	Product containing the notified polymer at 50-60% concentration
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
Exposure Period	0.5 hour
Concentration Range	Nominal: 100; 1,000; 10,000 mg/L
Remarks – Method	No significant deviations from the test guidelines were reported. The test substance was directly added to the test vessels.
RESULTS	
IC50	>10,000 mg/L (≡ > 5000 - 6000 mg/L notified chemical)
Remarks – Results	All validity criteria for the test were satisfied.
CONCLUSION	The test substance does not inhibit microbial respiration.
TEST FACILITY	Bayer (1998c)

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