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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Solsperse X300

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)
Orica Australia (ABN 99 004 117 828)
1 Nicholson Street
Melbourne VIC 3000

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical name, Other names, Molecular formula, Structural formula, Molecular weight, Spectral data, Import volume, Composition, Purity, Introduction and Use information.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting Point, Boiling Point, Density, Vapour Pressure, Water Solubility, Partition Coefficient, Adsorption/Desorption, Dissociation Constant, Particle Size, Flash Point, Flammability Limits, Autoignition Temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Solsperse X300

MOLECULAR WEIGHT
Mn >1000 Da

ANALYTICAL DATA
Reference NMR, IR, NMR, MS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95 %

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

DEGRADATION PRODUCTS
None under normal conditions of use. Under extreme heat (e.g. fire) the coatings and ink containing the notified polymer will burn and emit noxious fumes, including oxides of carbon and aldehydes.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Highly viscous opaque white liquid

Property	Value	Data Source/Justification
Melting Point	Not determined	Notified polymer is a highly viscous liquid.
Boiling Point	Not determined	Notified polymer decomposed prior to reaching boiling point (Lubrizol 2007).
Density	1000 kg/m^3 at 20°C	MSDS.
Vapour Pressure	<10^{-8} mmHg	Estimation of vapour pressure of polymers with MW > 1000 (US EPA, 2007).
Water Solubility	0.5 g/L at 20°C	Measured using the flask method with modifications. Moderately soluble.
Hydrolysis as a Function of pH	Not determined	A pH stability test over 2 weeks indicated a slight decrease in the weight-average molecular weight and changes to the infrared spectra of the notified polymer. The results were measured by GPC and FT-IR
Partition Coefficient (n-octanol/water)	Not determined	The water-oil partition coefficient is expected to be moderate based on the water solubility of the notified polymer.
Adsorption/Desorption	Not determined	Based on the moderate water solubility of the notified polymer and the potential cationic nature of the notified polymer, it is expected to partition to soil and sewage sludge.
Dissociation Constant	Not determined	Given the notified polymer contains a functional group likely to have a pKa around 10, the polymer is potentially cationic in environmental pH (4-9).
Particle Size	Not determined	Notified polymer is a liquid.
Flash Point	Not determined	Notified polymer is a highly viscous liquid at atmospheric pressure.
Flammability	Not determined	Not expected to be highly flammable.
Autoignition Temperature	Not determined	Not expected to autoignite.
Explosive Properties	Not determined	Not expected to be explosive based on structure.

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

Reactivity
Incompatible with halogens and halogenated compounds.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported by sea as a liquid containing > 95% notified polymer.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30-100	30-100	30-100	30-100	30-100

PORT OF ENTRY
Melbourne

IDENTITY OF RECIPIENT
Orica Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer (> 95%) will be transported in 20 or 180 kg open head steel drums by road and rail from

the port to the notifier's warehouse, before distribution to the customer sites. The reformulated products will be stored and transported in various containers including 1 L, 4 L, 10 L and 20 L steel cans, pails and drums.

USE
The notified polymer will be used as a dispersant for plastics and surface coatings at less than 10 % in UV cured coatings (approximately 70% of import volume) and gel coatings (approximately 30% import volume).

OPERATION DESCRIPTION
The imported polymer will be stored at the notifier's warehouse in Laverton, Victoria for distribution to customers. The products containing the notified polymer will be formulated by various companies at a number of sites located throughout Australia.

Gel & UV cured printing ink/coating formulation
Pigment Dispersion Stage
The pigment, resin and notified polymer are manually weighed and added or metered directly into the mixer and subjected to high speed sheer to produce a mill base.

Makeup Stage
The mill base is pumped into a large mixing vessel and the remaining resin and additive are added under constant stirring at low speed. Samples are removed at this stage for quality control testing in the laboratory, after which the batch is adjusted to meet specifications.

Filling Stage
The finished product containing the notified polymer is fed by gravity from the bottom of the mixing vessel through a filter and filling lines into containers. The closed containers are manually placed on pallets and taken by forklift to a warehouse for storage and distribution.

UV cured coating application
The coating containing < 10% notified polymer will be applied to metal, paper and plastic substrate by industry standard printing and coating techniques then exposed to ultraviolet light to be cured. The coating containers and the application machinery are washed and the aqueous wastes are collected by liquid waste disposal contractors.

Gel coat application
The coating containing < 10% notified polymer will be injected from the reservoir into the mould for plastics. The gel is used to coat the outside of the plastic. During the curing process the notified polymer binds to the coating matrix. The coating containers and the application machinery are washed and the aqueous wastes are collected by liquid waste disposal contractors.

The used gel and UV coating containers will either be washed on site or sent to licensed drum recycling contractors.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport workers	6-8	2-3	10-15
UV cured coating blending	4	8	50
UV cured coating laboratory workers	2	1	20
UV cured coating application	~200	4	260
Gel coating blending	4	8	80

EXPOSURE DETAILS

Transportation and storage

Workers involved in the transportation and storage of the notified polymer are not expected to be exposed to the notified polymer except in the unlikely event of an accident. However if a spill or leak were to occur, the warehouse is expected to have bunding to contain the liquid and adequate ventilation systems. Workers are expected to be trained in safe handling of chemical spills and have the MSDS readily available for emergencies.

Gel and UV cured coating formulation

Dermal and ocular exposure may occur as a result of drips and spills when weighing and charging the blending tanks and when taking samples from the blending vessels by laboratory technicians. During this process, workers are expected to wear PPE including gloves and safety glasses. Once blended, the coating solutions will be dispensed into containers via an automated filling system.

End use of gel and UV cured coatings.

The coating containing less than 10% of the notified polymer will be manually poured or pumped from containers into the reservoirs of the equipment used to apply the coatings. Any residual coating solution remaining in the container will be scraped from the container and added to the coating reservoir. During this process, dermal and accidental ocular exposure may occur and workers are expected to wear overalls, gloves, safety glasses. The application process is automated and exposure is not likely to occur.

The UV and gel coatings are cured by exposure to UV light and workers may experience UV radiation exposure to the skin and eyes. The end products will only be handled by workers after the coatings have cured at which time the notified polymer will be incorporated into a matrix with the substrate and no longer biologically available.

During cleaning and maintenance work, workers may be exposed to residual coating on equipment parts. Workers are expected to wear overalls, gloves and safety goggles during these activities.

6.1.2. Public exposure

The notified polymer will not be sold to the public. The public will come into dermal contact with the surface of the injection moulded and UV coated articles but will not be exposed to the notified polymer as it will be crosslinked to the matrix and not bioavailable.

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	non-irritating
Rabbit, eye irritation	slightly irritating

Toxicokinetics, metabolism and distribution

The notified polymer is expected to have moderate water solubility and moderate oil-water partition coefficients, which indicates the potential for permeation through the hydrophilic and hydrophobic layers of the skin strata and hence dermal absorption. However given the high molecular weight (> 1000 Da) of the majority of polymer species, it is unlikely that this dermal absorption will be significant. The notified polymer is not considered volatile based on the low estimated vapour pressure, however if inhalation of mists or aerosols containing the notified polymer were to occur, this could potentially lead to absorption across the respiratory tract epithelium.

Acute toxicity

In a study conducted on rats, there was no sign of systemic toxicity and no abnormalities were noted at necropsy. The notified polymer was found to be of low toxicity via the oral route in rats.

Irritation and sensitisation

The notified polymer was found to be non-irritating to the skin of rabbits after a single exposure in a dermal

irritation test. No tests were conducted on skin sensitisation. The notified polymer contains a structural alert for sensitisation and contains > 1% low molecular weight species with molecular weights less than 500 Da. Therefore the potential for skin sensitisation cannot be ruled out.

In an eye irritation test in rabbits, moderate conjunctival irritation symptoms were observed in all animals during the first 24 hours, but all lesions resolved by 72 hours. The notified polymer is considered slightly irritating to the eyes of rabbits.

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

Gel and UV cured coating
The manual weighing and charging process presents the greatest risk for workers through skin and eye exposure. Workers involved in all stages are expected to wear protective clothing, gloves and safety glasses. The notifier has stated that extraction ventilation will used at the weighing and charging station to minimise inhalation exposure to vapours and aerosols.

End use of gel and UV cured coatings
Workers involved in manually pouring or pumping the formulated product containing up to 10% notified polymer are at risk of skin and eye exposure, however gloves and safety glasses are expected to be worn. Following charging of the application, exposure is not likely to occur as the application process is automated and coatings are cured by UV light to form an inert matrix. Workers involved in UV curing are expected to wear UV radiation resistant glasses for eye protection.

Cleaning and maintenance
During equipment cleaning and maintenance work, there is the potential for dermal and eye exposure to residual coating material, particularly if water or solvents are used. It is anticipated that worker will wear overalls, gloves and safety glasses during cleaning and maintenance.

Overall, the risk to workers during weighing, charging and formulation is not unacceptable if the proposed engineering controls and protective equipment is used.

6.3.2. Public health
The public is likely to come into contact with finished surfaces of injection moulded and coated articles. However, the notified polymer will be crosslinked to the matrix and not bioavailable. Therefore the risk to the public is not unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will not be manufactured in Australia so there will be no release of the notified chemical due to this process. It will be reformulated into gel coatings and UV cured coatings and printing inks at several sites around Australia.

At the formulators' sites, release to the environment may occur in the unlikely event of an accident during transport or an accidental leak. It is estimated that a maximum of 0.5% of the notified polymer (~ 500 kg per year of notified polymer) would be lost due to spillage. Spills are to be prevented from entering drains or watercourses and are to be contained and soaked up with inert absorbent material (e.g. sand or soil) and placed in a sealable, labelled container for disposal in accordance with local regulations. It is expected it will be

disposed to landfill or thermally decomposed. A further 1% (1000 kg per year) of notified polymer is expected to be disposed to sewage when the residues in the drums have been washed out. A minor amount of waste from cleaning of equipment and filling lines during the coating manufacture will be disposed to landfill or thermally decomposed.

RELEASE OF CHEMICAL FROM USE

UV Cured Printing Inks/Coatings

The notifier has indicated that the UV cured coating applications containing the notified polymer will be applied to metal, paper and plastic substrates as printing inks and coatings. It's expected the coatings will occur at industrial sites since curing is part of the process. Residue from industrial applications will be captured and disposed to landfill. For application of coatings by rollers or dipping, the wastage figure is generally expected to be up to 2%. These wastes would be expected to be captured, solidified, and subsequently disposed of to landfill as solid wastes. Similarly, the wastage resulting from the application of inks to surfaces by the use of rollers may be up to 2% of the applied volume with the wastes captured and solidified for disposal to landfill. The inks/coatings are cured by exposure to UV light.

Gel Coatings

The gel coating containing the notified polymer will be injected into a mould to be used for injection moulding plastics to coat the outside of the substrate. During the curing process, the notified polymer will be bound with the coating matrix. Up to 2% (2000 kg) of the UV cured and gel coatings are expected to be spilt, then absorbed onto inert material and disposed to landfill. Up to 1% (1000 kg) of the notified polymer will remain in the containers and disposed to the sewage treatment plant.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer contained in the UV cured and gel coatings is irreversibly combined with other chemical substances as part of the manufacture of articles. The finished gel coated substrates will be disposed to landfill at the end of their useful lives. In the case of printing and coating applications, the notified polymer is immobilised within a UV-cured polymeric film on coated articles. The notified polymer will be disposed along with the used article at the end of its useful life, which, in the majority of cases, will be to landfill. In cases where UV-curable inks containing the notified polymer are used on paper, there is some potential for release of the notified polymer during the de-inking stage of paper recycling. However, very little of the notified polymer is expected to partition to the supernatant water which is released to the sewer. The notified polymer contained in coatings on metal substrates will be thermally decomposed during metal reclamation.

7.1.2 Environmental fate

No environmental fate data were submitted.

The majority of the imported quantity of notified polymer will be immobilised within the cured coatings on the articles or as solid waste. Hence, there are limited opportunities for release of the notified polymer to the environment except as a result of accidents. The ultimate fate of this portion of notified polymer will be determined by the fate of the articles and waste articles of which the majority is expected to be disposed to landfill. A small proportion of the notified polymer is expected to be thermally decomposed to water vapour and oxides of carbon and nitrogen during metal reclamation of the coated metal substrates at the end of their useful lives as well as waste from the formulators' sites and manufacturing plants.

The major proportion of the small quantity of notified polymer that may enter the sewage treatment plant as a result of the manufacturing process, prior to curing, is expected to mainly adsorb to sewage sludge since it is potentially cationic at environmental pH. This quantity of notified polymer will therefore be removed with sewage sludge and will not be released to aquatic ecosystems with the treated waste water. Similarly, any quantities of the notified polymer that may be released as a result of de-inking processes in paper recycling will associate with the sludge that is generated. This sludge will be dried and thermally decomposed or sent to landfill for disposal. A proportion of notified polymer in the uncured formulated product is expected to be disposed to landfill. Although the notified polymer is moderately water soluble, it is not expected to be overly mobile within soils and sediments as a result of its anticipated adsorption to soils. The notified polymer is expected to be degraded slowly in landfill by abiotic and biotic processes. Due to the high molecular weight of the notified polymer, it is expected bioaccumulation will not occur.

7.1.3 Predicted Environmental Concentration (PEC)

Based on the available information, a small quantity of the notified polymer (up to 2.5% of the annual import volume) could enter the sewage system annually as a result of the reformulation of the imported quantity of polymer into new liquid products or recycling of paper. However, this figure is likely to be an overestimate as these potential releases are expected to arise mainly from the disposal of liquid cleaning wastes from the reformulation sites, which, in modern facilities, is expected to be via an on-site solvent and insoluble solids removal system. Therefore the majority of the notified polymer collected from cleaning waste is expected to be disposed to landfill and not to the sewage. As discussed in Section 7.1.2, any quantities of the notified polymer in waste water entering a sewage treatment plant are expected to be removed with the bio-solids produced in such plants. The overall proportion of notified polymer that could enter aquatic ecosystems through the sewage treatment systems as a result of wastages from the reformulation process or paper recycling is therefore likely to be significantly below the nominal 2.5% release figure indicated above. As no significant environmental releases of the notified polymer are expected to occur based on the intended use pattern, no PEC has been calculated.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. The notified polymer contains potentially cationic functionalities which may exhibit toxicity to aquatic organisms.

7.2.1 Predicted No-Effect Concentration

A PNEC cannot be calculated as no aquatic toxicity data are available.

7.3. Environmental risk assessment

Although the notified polymer has potential to exhibit toxicity to aquatic organisms, it is not expected to enter the aquatic environment in significant quantities when it is used as intended as gel coatings for injection moulding plastics and UV cured printing inks and coatings for metal, paper and plastic articles. Therefore, the notified polymer is not considered to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

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

Although the notified polymer has potential to exhibit toxicity to aquatic organisms, based on its reported use patterns it 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 to the notified polymer during weighing and charging:
  - Extraction ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Single-use chemical resistant gloves
  - Coveralls
  - Safety glasses
  - Closed or safety footwear

  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 to landfill.

Storage

- The following precautions should be taken regarding storage of the notified polymer:
  - Store away from halogens and halogenated compounds

Emergency procedures

- Spills or accidental release of the notified chemical 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 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; or

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of plastics and surface coatings, or is likely to change significantly;

- the amount of chemical being introduced has increased from 100 tonnes, or is likely to increase, significantly;
- if 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 chemical 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 0.5 g/L at 20°C

Method OECD TG 120 Solution/Extraction Behaviour of Polymers in Water
Remarks Flask Method with modifications. The test was conducted at pH 7 and the measurements were made in triplicate.
Test Facility Lubrizol (2009)

Hydrolysis as a Function of pH

pH Stability Test results (over 2 weeks):
1a. Decrease in % Mw ranged 23.8 – 54.5% over environmental pH (4 – 9).
1b. Decrease in % Mn ranged 5.5 – 19.6% over environmental pH.

2. Appearance of weak carbonyl absorption band at 1672 cm^{-1} over environmental pH.

Method A pH stability test was performed using the flask method with modifications, based on OECD TG 120

1. GPC measurements – OECD Guideline 118
2. FT-IR measurements.

pH	*Change in %Mw*	*Change in %Mn*	*Change in IR*
4	-54.5	-19.6	Appearance of band at 1672 cm^{-1}
7	-24.2	-5.9	Appearance of band at 1672 cm^{-1}
9	-23.8	-5.5	Appearance of band at 1672 cm^{-1}

Remarks A very slight decrease in the change in the percentage of number-average molecular weight (Mn) combined with a small decrease in the change in the percentage of weight-average molecular weight (Mw) as well as changes in the IR spectrum indicates some chemical transformation, possibly hydrolysis, of the notified polymer is occurring over environmental pH (4 – 9).
Test Facility Korea Polymer Testing & Research Institute Ltd (2008)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Method. EC Directive 2004/73/EC B.1 *bis* Acute Toxicity (Oral).
Species/Strain	Rat/Sprague-Dawley CD(Crl: CD (SD) IGS BR)
Vehicle	Dimethyl sulphoxide. The test substance did not dissolve/suspend in distilled water or arachis oil BP.
Remarks - Method	A total of 5 females were dosed at 2000 mg/kg by oral gavage.
RESULTS	
LD50	> 2000 mg/kg bw
Signs of Toxicity	No signs of toxicity were observed.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	There were no deaths and all animals showed expected body weight gain.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	SafePharm Laboratories (2008a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None. The notified polymer was applied directly to skin.
Observation Period	1- 72 hours.
Type of Dressing	Semi-occlusive.
RESULTS	
Remarks - Results	There was no evidence of skin irritation (score 0) during the study.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	Safepharm (2008b)

B.3. Irritation – eye

TEST SUBSTANCE	Notified polymer
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	3

Observation Period 7 days

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	1.67	1	1	2	< 7 days	0
Conjunctiva: chemosis	0.67	0.33	0.33	2	< 72 hrs	0
Conjunctiva: discharge	1	1	1	2	< 72 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 Moderate conjunctival redness, chemosis and discharge (score 2) was observed in all animals 1 and 24 hours after treatment, except chemosis, which had reduced to slight swelling at the 24 hour observation. At 48 hours, slight chemosis and discharge was noted but the level of redness remained moderate. All conjunctival symptoms cleared by 72 hours with the exception of slight redness, which cleared by day 7.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Safepharm (2008c)

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