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April 2009

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

FULL PUBLIC REPORT

Polymer in DISPERBYK-168

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**

TABLE OF CONTENTS

| | |
|---|----|
| <u>FULL PUBLIC REPORT</u> | 3 |
| 1. APPLICANT AND NOTIFICATION DETAILS..... | 3 |
| 2. IDENTITY OF CHEMICAL | 3 |
| 3. COMPOSITION..... | 4 |
| 4. PHYSICAL AND CHEMICAL PROPERTIES..... | 4 |
| 5. INTRODUCTION AND USE INFORMATION..... | 4 |
| 6. HUMAN HEALTH IMPLICATIONS | 6 |
| 7. ENVIRONMENTAL IMPLICATIONS | 8 |
| 8. CONCLUSIONS AND REGULATORY OBLIGATIONS..... | 9 |
| <u>APPENDIX A: TOXICOLOGICAL INVESTIGATIONS</u> | 12 |
| <u>BIBLIOGRAPHY</u> | 14 |

FULL PUBLIC REPORT

This assessment report is for an extension of original assessment certificate for Polymer in DISPERBYK-168. Based on the submission of new information by the extension notifier, some sections of the original assessment report for Polymer in DISPERBYK-168 have been modified. These modifications have been made under the heading 'Extension Applicant' in the respective sections.

Polymer in DISPERBYK-168

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Holder of the original assessment certificate (No.2711, LTD/1350)

Nuplex Industries (Aust) Pty Ltd (ABN 25 000 045 572)

49-61 Stephen Road

BOTANY, NSW 2019

Holder of the original assessment certificate (No.2712, LTD/1350)

FUJIFILM Sericol Australia Pty Limited (ABN 66 075 733 069)

4 Coronation Avenue

KINGS PARK, NSW 2148

Applicant for an Extension of the Original Assessment Certificate:

Cintox Australia Pty Ltd (ABN 63 122 874 613)

Suite 1, Level 2, 38-40 George Street

PARRAMATTA, NSW 2150

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 formula, Structural formula, Molecular weight, Spectral data, Methods of detection and determination, Impurities, Additives/Adjuvants, Introduction volume, Details of use, Identity of manufacturer/ recipients, and Polymer constituents.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Melting point/Freezing point, Boiling point, Density, Vapour pressure, Water solubility, Hydrolysis as a function of pH, Partition coefficient (n-octanol/water), Adsorption/Desorption, Dissociation constant, Particle size, Flammability limits, Autoignition temperature, Explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES:

United States of America (P-98-696 in 1998), Canada (NSN 11959 in 2002), China (2002)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

DISPERBYK-168 (at concentrations of <40%)

MOLECULAR WEIGHT

>1000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Soft colourless solid crystals

| Property | Value | Data Source/Justification |
|---|---|--|
| Melting Point | expected to be >25 °C | Estimated |
| Density | 1110 kg/m ³ | Based on the density of DISPERBYK-168 (MSDS). The notified polymer is never isolated from solutions. |
| Vapour Pressure | <1.3 x 10 ⁻⁹ kPa | Estimated based on molecular weight |
| Water Solubility | Insoluble | Estimated based on its structure. |
| Hydrolysis as a Function of pH | Significant hydrolysis is unlikely to occur in the environmental pH range of 4-9 | Estimated based on its structure. |
| Partition Coefficient (n-octanol/water) | >4 | Estimated (US EPA, 2006) and also based on its low water solubility. |
| Adsorption/Desorption | Expected to be immobile in soil associated with soil and sediment due to its low water solubility | Estimated |
| Dissociation Constant | Unlikely to dissociate | Estimated based on its low water solubility. |
| Particle Size | Not determined | Never isolated from solutions |
| Flash Point | >100°C | Measured |
| Flammability | Not expected to be highly flammable | Estimated |
| Autoignition Temperature | Not expected to be auto ignited | Estimated |
| Explosive Properties | Not expected to be explosive | Estimated |

DISCUSSION OF PROPERTIES

The water solubility is estimated to be low because the chemical structure of the polymer includes hydrocarbon chains and aromatic rings which have low water solubility. Most of the other functional groups present throughout the structure are unlikely to contribute significantly to the water solubility of the notified polymer.

Although significant hydrolysis is unlikely to occur in the environmental pH range of 4-9, the notified polymer contains linkages that may hydrolyse under extreme pH.

Although the notified polymer is unlikely to dissociate, it contains functionalities that are likely to become cationic at neutral to acidic pH.

No degradation products and no loss of monomers, other reactants, additives, or impurities is expected under normal conditions of use.

Reactivity

Stable under normal conditions of use. Contact with strong oxidizing agents should be avoided when using or storing DISPERBYK-168.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. It will be imported into Australia as a component of an ink or coating additive DISPERBYK-168 (at concentration of < 40%) by sea freight. The notified polymer may also be imported as a component of finished coating formulations (at concentration of < 25%) or printing inks (at concentration of < 5%).

Extension Applicant:

The notified polymer will not be manufactured or reformulated within Australia. The notified chemical will be imported in printing ink at concentrations of $\leq 10\%$.

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> | <1 | 1-3 | 1-3 | 3-10 | 3-10 |
| <i>Extension</i> | 1 | 2 | 3 | 4 | 5 |

PORT OF ENTRY

All major sea ports throughout Australia.

Extension Applicant:

Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

Nuplex Industries (Aust) Pty Ltd.

Extension Applicant:

Cintox Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The product containing the notified polymer will be imported in sealed 25 kg or 200 kg steel drums. They will be transported by road or rail to the notifier's storage warehouse before distributed to reformulation and/or end user sites. The packaging sizes of the formulated products are 5 L or 1 L polyethylene containers.

Extension Applicant:

The imported formulated products containing the notified polymer at concentration of $\leq 10\%$ will be packaged in 1 to 5 L polyethylene containers and transported by road or rail to the notifier's warehouse before being distributed to end users.

USE

The notified polymer will be used as an active component (<40%) of a wetting and dispersing additive, DISPERBYK-168, used in industrial coatings (majority) and printing inks. Concentrations of the notified polymer are likely to be <25% in finished coating products and <5% in finished printing inks. The coating product will be used in industrial applications including timber furniture, paper, plastics, and metals. Inks are for use in printing industrial materials such as labels and advertising materials.

Extension Applicant:

Additive in printing ink at concentrations of up to 10%.

OPERATION DESCRIPTION

Reformulation

When the notified polymer is imported as a component of finished coatings or printing inks, there will be no reformulation or repackaging of the notified polymer. The finished product will be directly sold to end users for applications.

When the notified polymer is imported as the active ingredient in DISPERBYK-168, the imported product will be blended into the finished coating product and printing ink at formulation sites using essentially the same processes. DISPERBYK-168 will be only added to the millbase (a dispersion of pigments in a solvent) under mechanical agitation, via pipes and pumps. Any solvents or resins that are required for the production of the finished product will be premixed. Following the complete incorporation of DISPERBYK-168 in enclosed mixing vessels, any additional pigments will be added. The finished formulations will likely be sampled and tested by in-house laboratories. The finished formulation will be then transferred through pipes to containers that are sealed and labelled before distribution to end-users.

All equipment will be cleaned using solvents, usually mineral spirits. Mixing vessels and transfer lines will be rinsed with mineral spirits. All washings will be stored in holding tanks on-site that will be routinely emptied by licensed waste contractors for disposal.

End uses*Coating applications:*

The finished coatings (containing <25% notified polymer) will be applied onto substrates by mainly airless and conventional spray guns (>95% of the applications) or rollers and brushes (<5%). Automatic sprays (i.e. robotic devices that apply the coatings in an enclosed room) will be used wherever possible. Then the coating will be cured via UV lights. The curing time varies but may be as little as 10 seconds. All spray applications will occur in designated spray booths and are best suited for intricate and detailed furniture. Any overspray will be collected onto craft paper and disposed of to landfill after curing or incinerated. Application by roller and brush will be a manual operation, mainly conducted at open air sites or sites with general ventilation. This minor way of application will be mainly for flat-panel substrates.

Printing ink applications:

When used in the printing industry, the ink formulation (typically containing <5% of the notified polymer) will be transferred to labelling machines via automated lines from drums. The labelling machine will be fully automated and is equipped with UV lamps that cure the product immediately.

Extension Applicant:

The notified chemical will be imported in printing ink at concentrations of $\leq 10\%$ and will not be reformulated within Australia. The imported printing ink will be transferred from the bottles to the printing machine via automated lines. The printing machines will be automated with the ink cured by UV lamps after coating with local exhaust ventilation present.

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 per day)</i> | <i>Exposure Frequency (days per year)</i> |
|-------------------------------|---------------|--|---|
| Waterside workers | 10 | 4 | 50 |
| Storage & transport personnel | 70 | 4 | 150 |
| Reformulation | | | |
| - production of coatings | 40 | 5 | 200 |
| - production of inks | 40 | 5 | 200 |
| - quality control | 10 | 2 | 100 |
| End uses | | | |
| - coatings | 100 | 6 | 250 |
| - printing inks | 20 | 8 | 250 |

Extension Applicant:

| <i>Category of Worker</i> | <i>Number</i> | <i>Exposure Duration (hours per day)</i> | <i>Exposure Frequency (days per year)</i> |
|-------------------------------|---------------|--|---|
| Waterside workers | 6 | 2 | 12 |
| Storage & transport personnel | 20 | 2 | 50 |
| Printer operators | 20 | 6 | 200 |
| Service technicians | 5 | 1 | 50 |

EXPOSURE DETAILS

Occupational exposure to the notified polymer during importation, transportation or storage is unlikely except in the event of accidents.

Reformulation

With the enclosed processes and other engineering controls such as general exhaust ventilation, potential worker exposure to the notified polymer via the dermal, ocular and inhalation routes will be restricted to accidental spills or leakages during connections or disconnections of transfer lines and during sampling. In

addition, workers involved in the reformulation processes, especially during the transfer process, will wear safety glasses, coveralls and chemical-resistant gloves to protect against possible spills or splashes. Therefore, worker exposure during reformulation is expected to be low.

End uses

Coating Applications

During application using spray guns, worker exposure will be limited as all spray applications will occur in designated spray booths. The personnel involved in this type of application will be appropriately trained and qualified. The minimum personal protection equipment (PPE) that will be worn includes safety glasses, coveralls, and chemical-resistant gloves and, if necessary, an air respirator. Worker exposure will be minimal when automatic sprays are used.

For roller or brush based manual applications, exposure to the notified polymer via dermal, ocular and inhalation may occur before the coating is cured under UV light. Use of PPE such as overalls, eye protection and impermeable gloves and the general ventilation in place during manual applications will reduce the potential exposure.

Printing Ink:

Exposure to the notified polymer when used in printing inks will be unlikely due to the automated and enclosed processes. Possible exposure may result via the dermal or ocular routes during connection and disconnection of lines from containers of ink formulation to the labelling machine. However, exposure to the notified polymer will be limited by PPE worn by workers such as overalls, impermeable gloves and eye protection.

Extension Applicant:

Printer operators will be exposed to the notified chemical during connection and disconnection of the transfer lines and service technicians during printer maintenance. Dermal exposure is expected to be greatest with ocular and inhalation exposure also possible. However, exposure will be limited through the use of local exhaust ventilation and the use of personnel protective equipment by workers.

6.1.2. Public exposure

The notified polymer, as imported, is not available to the public. The general public are only expected to come into contact with the notified polymer after the ink or coating formulation is cured to the substrate. Therefore, public exposure is expected to be negligible.

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 A.

| <i>Endpoint</i> | <i>Result and Assessment Conclusion</i> |
|--------------------------|---|
| Rat, acute oral toxicity | oral LD50 >5000 mg/kg bw; low toxicity |
| Rabbit, skin irritation | non-irritating |
| Rabbit, eye irritation | slightly irritating |

No data on toxicokinetics, metabolism and distribution were provided. Based on its properties, the notified polymer will have limited absorption via the skin and inhalation due to its low water solubility, high log P_{ow} (>4), low vapour pressure, and high molecular weight.

The notified polymer is of low acute oral toxicity (oral LD50 = >5000 mg/kg/day). No data on acute dermal or inhalation toxicity were provided.

The notified polymer was found to be not irritating to the skin. The eye irritation study found very slight conjunctival redness and increased secretions in all test animals up to 8 hours and disappeared by 24 hours after administration of the test substance (solid crystals). It is likely that this effect might have been due to mechanical abrasion rather than chemical irritation. Nevertheless, the severity of this effect does not meet the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

No data on sensitisation, repeated dose toxicity, genotoxicity or carcinogenicity were provided for the notified polymer. A literature search did not locate any toxicity data on the notified polymer. Therefore, the systemic

toxicities are unknown. However, based on its limited systemic absorption and absence of structural alerts, the notified polymer is not expected to present significant systemic toxicity.

Classification

Based on the limited 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

Based on the available data, the main health concern to the workers who will handle the product containing the notified polymer is the potential risk of slight eye irritation from spills and splashes, especially during reformulation when connection and disconnection of transfer lines occur and during manual applications of coating products by rollers and brushes. However, the risk of slight eye irritation is expected to be limited due to low frequencies of these processes, short exposure duration (for connection and disconnection of transfer lines) and use of PPE at workplaces. The enclosed nature of other processes will restrict the risk of slight eye irritation. Employers should implement necessary control measures to minimise ocular exposure.

6.3.2. Public health

As there will be no exposure of the public to the notified polymer, the risk of slight eye irritation to the public from exposure to the notified polymer is considered to be negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

During reformulation of the coating or ink products, an estimated 1% of the total importation volume of the notified polymer may be regarded as spilt wastes. The spills will be readily contained and collected for adequate disposal to landfill or incinerated.

At most, 1% of the total importation volume of the notified polymer is anticipated to remain in the storage containers as residues. The storage containers will be cured prior to disposal to landfill.

Formulation equipment is rinsed with solvents. It is predicted that less than 1% of the annual importation volume of the notified polymer will be lost to washing the manufacturing equipment. These washings are stored in holding tanks on-site for disposal by licensed waste contractors.

RELEASE OF CHEMICAL FROM USE

When coating formulations containing the notified polymer are applied by spray techniques, it is anticipated that approximately 25 - 50% of the coating product will form overspray and be collected as waste material. As the application of coatings is conducted at industrial sites in designated spray booths, the overspray will be captured in the spray booth and on craft paper. The product will then dry onto the paper and be disposed of to landfill or incinerated.

It is estimated that less than 1% of the notified polymer contained in coating products applied by brush or roller would be lost due to cleaning of the application equipment. Washings will be collected and disposed of by licensed waste contractors.

Release of the notified polymer from use as a printing ink is expected to be low as minimum wastes would be generated. Wastes in this case may be generated when the finished ink formulation is transferred to the labelling machine. Once in the machine, the ink is directly applied to the carton substrate and immediately cured/dried.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer will be disposed of to landfill or may be incinerated. Products containing the notified polymer are likely to end up in landfill at the end of their useful life.

Residues of the notified polymer that remain in empty storage containers will ultimately be disposed of to landfill. Leaching of the polymer from landfill is unlikely given the expected low water solubility of the notified polymer.

Industrial washings are stored in holding-tanks on-site for disposal by licensed waste contractors.

7.1.2 Environmental fate

No environmental fate data were submitted.

The notified polymer is expected to be hydrolytically stable. Due to its hydrophobic nature, it is expected that the notified polymer in landfill will associate with sediments and organic phases of soil and sediments, and slowly degrade to simple carbon compounds.

The products containing the notified polymer are likely to be used throughout Australia. The major environmental exposure is expected to be due to the disposal of waste, from the coatings manufacture and particularly from overspray during application, to landfill. If spilt on land, the notified polymer is expected to become immobilised in the soil layer. Due to its low water solubility, the polymer will remain bound within the soils and sediments of the landfill and to be slowly degraded by abiotic processes.

While environmental exposure is limited during the printing process, the total import volume of the notified polymer will ultimately be disposed of in either landfill or be incinerated. The widespread use pattern indicates that landfills throughout Australia would receive the notified polymer as residues in the original packaging and on paper products. The residual ink would be expected to remain within the packaging unless breached. On paper the notified polymer will interact with other components to form a stable polymer matrix and, once dry, is expected to be immobile and pose little risk to the environment.

During recycling processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. These aqueous wastes are expected to go to sewer. Very little of the notified polymer is expected to partition to the supernatant water which is released to the sewer. Sludge generated during the washing process is dried and incinerated or sent to landfill for disposal.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. The notified polymer is potentially cationic at neutral to acidic pH and therefore can be toxic to algae. However, limited aquatic exposure is expected.

7.3. Environmental risk assessment

The notified polymer will be a component of formulated ink preparations. Once these inks have been used in order to print documents such as labels and advertising materials the notified polymer is expected to remain within the article matrices. Hence, the majority of the notified polymer will share the fate of the printed or coated articles into which it is incorporated. It is anticipated that these articles will be disposed of by landfill or incinerated after use.

In landfill, it is expected that the notified polymer will remain immobile within the matrices. Incineration of the notified polymer will result in the formation of water vapour and oxides of carbon.

Paper recycling will result in the notified polymer ending up as a sludge which is then disposed of as landfill or incinerated by licensed waste contractors.

Given the widespread and disperse environmental exposure, together with the low expected toxicity, the notified polymer is not considered to pose a risk to the environment when it is stored, transported and used in the proposed manner.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

Human health risk assessment

Under the conditions of the occupational settings described, together with the recommended control measures, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

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

Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Risk assessment (extension application)

The proposed use and fate of the notified polymer will not change under the proposed extension. The circumstances in the extension application are not expected to impact on the original human health and environment risk assessment. Therefore there are no changes required in the risk assessment.

Recommendations**CONTROL MEASURES****Occupational Health and Safety**

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Prevent leaks and spills.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid contact with eyes;
 - A eye wash station should be available;
 - Avoid spills and splashing during use.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Eye protection.

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.

Environment

- The notified polymer should be disposed to landfill.
- Keep containers in a cool, dry well ventilated area.
- Place inert absorbent material onto spillage. Use clean non-sparking tools to collect the material and place into a suitable labelled container.

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;
 - imported in any form other than in solution.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 and printing inks, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 10 tonnes, 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 notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

| | |
|------------------|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 401 Acute Oral Toxicity – Limit Test. |
| Species/Strain | Rat/ SPF Wistar. |
| Vehicle | Olive oil. |
| Remarks – Method | No significant protocol deviations. |

RESULTS

| <i>Group</i> | <i>Number and Sex of Animals</i> | <i>Dose mg/kg bw</i> | <i>Mortality</i> |
|--------------|--------------------------------------|--------------------------|------------------|
| I | 3 per sex | 2000 | 0/6 |
| II | 3 per sex | 5000 | 0/6 |

LD50 >5000 mg/kg bw

Signs of Toxicity Animals dosed at 5,000 mg/kg bw displayed apathy within 4 hours of intubation. This was attributed to dosing of the test substance with an oil-based vehicle.

No treatment-related effects on weight gain, water or food consumption were observed.

Effects in Organs No treatment related pathological or macroscopic effects.

Remarks – Results No mortality occurred in test animals throughout the duration of the test (14 days).

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

TEST FACILITY Pharmatox (1998)

B.2. Irritation – skin

| | |
|--------------------|--|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 404 Acute Dermal Irritation/Corrosion. |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Vehicle | None (solid crystal applied) |
| Observation Period | 7 days |
| Type of Dressing | Semi - occlusive |
| Remarks – Method | No significant protocol deviations. |

RESULTS No signs of skin irritation were observed in test animals. No treatment-related effects on weight gain or behaviour were observed.

CONCLUSION The notified polymer is non-irritating to skin.

TEST FACILITY Pharmatox (1997a)

B.3. Irritation – eye

| | |
|-------------------|--|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 405 Acute Eye Irritation/Corrosion |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |

| | |
|--------------------|---|
| Observation Period | 72 hours |
| Remarks – Method | No significant protocol deviations. Solid crystal was cut into small pieces and applied directly to the conjunctival pouch. |
| RESULTS | Very slight conjunctival redness and increased secretions were observed in all test animals up to 8 hours and disappeared by 24 hours after administration of the test substance. |
| Remarks – Results | There were no treatment-related effects in body weight gain. It is likely that this effect might have been due to mechanical abrasion rather than chemical irritation. |
| CONCLUSION | The notified polymer is slightly irritating to the eye. |
| TEST FACILITY | Pharmatox (1997b) |

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