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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Beckopox EP386w/52WA Epoxy Resin

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

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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)
Cytec Australia Holdings Pty Ltd (ABN: 45 081 148 629)
Suite 1, Level 1 Norwest Quay, 21 Solent Circuit, Norwest Business Park
Baulkham Hills NSW 2153

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, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details, import volume and site of formulation

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Freezing point, Boiling Point, Density, Vapour Pressure, Hydrolysis as a Function of pH, Partition Co-efficient, Adsorption/Desorption, Dissociation Constant, Particle Size, Flash Point, Autoignition Temperature and Explosive Properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Beckopox EP386w/52WA (product containing the notified polymer at < 50%)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR, HPLC and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 70%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer is imported and applied in liquid form. Residual monomers and impurities could be lost from the coatings through evaporation or leaching.

DEGRADATION PRODUCTS
Not known.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: viscous liquid (product* is an off-white milky dispersion)

Property	Value	Data Source/Justification
Freezing Point	0°C	MSDS*
Boiling Point	100°C at 101.3 kPa	MSDS*
Density	1080 kg/m^3 at 20°C	MSDS*
Vapour Pressure	Not determined	The notified polymer is estaimated to be very slightly volatile given its molecular weight of > 1000 Da.
Water Solubility	≤ 4.3 × 10^{-3} g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable groups, however, due to its limited water solubility, hydrolysis is expected to be very slow in the environmental pH range (4 – 9) at ambient temperature.
Partition Coefficient (n-octanol/water)	log Pow = 3.80 at 25°C	Measured
Adsorption/Desorption	Not determined	The notified polymer is expected to sorb to sludge, soil and sediment based on its limited water solubility and high molecular weight.
Dissociation Constant	Not determined	Dissociation is not expected under normal conditions since no readily dissociable functions exist in the notified polymer.
Particle Size	Not determined	Liquid
Flash Point	> 100°C (pressure unknown)	MSDS* (DIN EN ISO 2719)
Flammability	Not expected to be highly flammable	Based on flash point.
Autoignition Temperature	Not determined	The notifier has stated that the polymer is not expected to self-ignite.
Explosive Properties	Not determined	No information was provided for explosive properties of the notified polymer, however, it contains epoxy groups that would imply explosive properties.

*For Beckopox EP386w/52WA.

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 use conditions. It reacts with the second part of the coating during end-use application.

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a component of a water dispersible, liquid epoxy resin (containing < 50% notified polymer).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 10	< 20	< 30	< 50	< 100

PORT OF ENTRY
Sydney or Melbourne

IDENTITY OF RECIPIENTS
A number of customers will formulate Beckopox EP 386w/52WA into primer coatings.

TRANSPORTATION AND PACKAGING
The imported product containing < 50% notified polymer in 200 kg metal drums will be transported by road from port(s) of entry to Cytec warehouses and then transported by road to customers for formulation. After formulation, the formulated coatings in various sized containers ranging from 2 L metal cans to 200 L steel drums are transported to the end users by road.

USE
The notified polymer will be used as a component of one part of a 2-part epoxy coating used as an industrial primer.

OPERATION DESCRIPTION
Formulation
At the formulation sites, imported product in closed head 200 L steel drums will be transferred from a pallet by forklift from the warehouse area to the mixing area. The drums will be fitted to transfer lines through hose and pump and the required amount of product will be directly fed to the mixing vessel where other ingredients will also be added to make the finished coating product. The transfer equipment and mixing vessel are an enclosed system located in a bunded area with minimal potential for losses during these operations. Following the mechanical blending of imported material and the other coating ingredients, quality control testing of a sample of formulated coatings will be manually conducted.

End use
For large scale spray applications, the formulated coating containing the notified polymer will be pumped from large scale containers into a holding tank where it will be automatically mixed with the second part of the coating. For small scale applications, the decanting and mixing will be done manually.

The end use coatings containing the notified polymer at < 50% will be applied to metal (main use), plastic and concrete structures mainly by spray in a spray booth or outdoors. When used outdoors, a cloth or plastic drop sheet will be used to collect any minor drips. Roller and brush may be used on small jobs or for touch-up.

The range of structures coated include concrete and paving slabs, plastic vehicle components, such as bumper bars, and steel structures such as cars, trucks, and industrial machine parts.

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 and storage of imported product	10-20	4-8	200
Coating formulation – product blending	100	8	200
Coating formulation – quality control	1-2	1	200
Coating formulation – product packaging	100	8	200
Transport and storage of formulated coatings	10-20	4-8	200
Coating application	200	8	200

EXPOSURE DETAILS

Transport and warehousing

Workers are not expected to be exposed to the imported product containing the notified polymer (< 50%) during transport and stroage, as they will be handling closed containers. Exposure is possible in the event of an accident where the packaging is breached.

Product blending

Workers involved in the blending of the imported product and product packaging may have dermal or ocular exposure to the notified polymer (< 50%) though drips and spills during transfer of product into the mixing vessel and packaging. This may occur while connecting/disconnecting hoses or through splashes occurring during pouring and packaging. Inhalation exposure to the notified polymer is not expected unless aerosols or mists are generated during processes. The exposure will be limited by the engineering controls employed, such as the use of automated pumping equipment, sealed blending vessels, bunded mixing area, local and general ventilation and personal protective equipment (PPE) worn by workers.

Workers involved in quality control may be exposed dermally to the formulated coating containing the notified polymer at < 50% during sampling and testing. The exposure will be minimised by the use of PPE and local and general ventilation.

End use coating application

During end use in spray booth, workers may be exposed to the formulated coating containing the notified polymer at < 50% during connecting and disconnecting drums to pumping equipment and during troubleshooting and cleaning of spray equipment where entry into the non-operating spray booth may be required. Exposure during spray application by the end users may occur via the dermal, ocular and inhalation routes. However, exposure should be reduced by the expected use of PPE and engineering controls, such as use of spray booths.

When Beckopox EP 386w/52WA is applied by spray outdoors, workers will wear a suitable respirator, overalls, gloves and safety glasses. Where possible, workers will stand up-wind from the direction of the spray.

Dermal and ocular exposure to the notified polymer may occur when the coatings are applied by brush or roller.

After spray application to the metal, plastic and concrete components, the coating containing the notified polymer is dried and forms a coating and is not expected to be bioavailable in this form..

6.1.2. Public exposure

Public exposure to the notified polymer or the uncured coatings containing the notified polymer is not expected under normal use conditions as it is used only in industrial settings. Exposure to the notified polymer could occur if an accident occurred in transport. Although the public may have contact with articles to which the coating has been applied, after curing the notified polymer will be bound to the substrate surface and not available for exposure. Since the coating will be used as a primer, subsequent top coats will cover the primer layer and further reduce public exposure.

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	*Test substance*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Notified polymer	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	Beckopox EP386w/52WA	slightly irritating
Rabbit, eye irritation	Beckopox EP386w/52WA	slightly irritating

Toxicokinetics and distribution.

Based on the high molecular weight (NAMW > 1000 Da), low water solubility and expected high lipophilicity, absorption across biological membranes is expected to be low. However the polymer contains a significant proportion of species with NAMW < 1000 Da, which may be absorbed.

Acute toxicity

The notified polymer is of low acute toxicity *via* the oral route. No acute dermal or inhalation toxicity data was provided for the notified polymer.

Irritation and sensitisation
The notified polymer at 30-50% was slightly irritating to the eyes and non-irritating to skin based on studies in Beckopox EP386w/52WA.

No data on sensitisation were provided for the notified polymer. A Buehler test for skin sensitisation provided for a product containing a similar polymer at approximately 50% showed negative results, however, this polymer has higher NAMW and lower percentage of low molecular weight species < 1000 Da and 500 Da than the notified polymer.

The notified polymer contains epoxide groups that are a structural alert for sensitisation (Barratt et al. 1994, Gerner et al. 2004 and Hulzebos et al. 2005). Species of low molecular weight (< 1000 Da) have a higher sensitising potential compared with oligomers of higher molecular weight (HSE, 2003). Given the notified polymer contains a significant percentage of low molecular weight species (< 1000 Da) it may possess some sensitising properties.

Mutagenicity, carcinogenicity and toxicity for reproduction
The notified polymer contains an epoxy functional group that is a structural alert for cancer, reproductive effects, and perhaps genotoxicity (USEPA 1995 and 2010). The USEPA considers that structures with epoxy equivalent weights of > 1,000 Da are presumed not to pose a hazard under any conditions. The functional group equivalent weight of the notified polymer is approximately 500 Da (information provided by the notifier), suggesting that the potential for adverse health effects cannot be ruled out. However the functional group equivalent weight of the product as imported is approximately 1000 Da, thus reducing the likelihood of such effects.

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

However, based on a structural alert (epoxy groups) and the presence of low molecular weight species, the potential for adverse health effects cannot be ruled out.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The notified polymer is expected to be slightly irritating to eyes and non-irritating to the skin. It may have the potential to cause sensitisation.

There is a possibility of ocular and dermal exposure to the notified polymer at < 50% during connection of pumping lines to the steel drums in coating formulation, and up to 50% during cleaning of mixing tanks and coating application. However, the expected use of PPE by workers should minimise exposure during these activities.

When exposure of workers to the notified polymer during formulation and end use is mitigated through the use of engineering controls such as coating being carried out in spray booth and personal protective equipment, the occupational health and safety risk of the notified polymer is considered to be low.

The risk for workers is considered to be greatest where inhalation exposure to the notified polymer is not controlled by engineering controls, e.g., during spray applications outside. During these processes, PPE is required to minimise worker's exposure to the notified polymer and thus the health risk to workers.

Overall, provided workers wear PPE, the risk to workers health from use of the notified polymer is not considered unacceptable.

6.3.2. Public health

As no exposure is expected from the cured coated material, the risk to the public from the use of the notified polymer is low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The imported notified polymer will be formulated and decanted into end-use containers in Australia. The notified polymer is anticipated to be released to the environment from accidental spills (< 1% of annual import volume), or as residue (2%) remaining in transport containers and formulation equipment. Approximately 0.1% of the annual import volume of the notified polymer may be released to sewer from the cleaning of equipment, however the majority of notified polymer will be collected with solvent and recycled into subsequent batches. Solid waste is expected to be disposed of to landfill and notified polymer residue in empty import containers is likely to be thermally decomposed during metal reclamation processes.

RELEASE OF CHEMICAL FROM USE

The end-use product containing the notified polymer is expected to be applied in industrial settings to various substrates including concrete and plastic, but mainly to metal. Application will typically be by spray painting in spray booths and outdoor settings, although brush and roller may be used. Overspray is anticipated to account for up to 50% of the annual import volume, depending on the size and shape of the article being sprayed. In the spray booths this is likely to be captured by standard engineering controls and recycled into the next batch or, after being allowed to cure, disposed of to landfill. In outdoor settings overspray is likely to be captured by paper, which will be disposed of to landfill, or caught in bunded areas. Application equipment will be cleaned using solvent, and it is expected that the solvent will be recycled into the next batch, and the solid waste will be disposed of to landfill. Residual product in end-use containers is expected to be thermally decomposed during metal reclamation processes or disposed of to landfill with the empty containers.

RELEASE OF CHEMICAL FROM DISPOSAL

Notified polymer in coatings is expected to share the fate of the substrate to which it has been applied. Notified polymer in coatings applied to metal articles will be either thermally decomposed during metal reclamation processes at the end of the articles useful life, or disposed of to landfill. Cured coating removed by physical means (e.g. sandpaper/scraping) and non-metal articles at the end of their useful life are expected to be disposed of to landfill.

7.1.2 Environmental fate

The notified polymer is not expected to be readily biodegradable. This is supported by a ready biodegradability test report on a product which contains < 50 % notified polymer (NOTOX 2010a). The product was not found to be readily biodegradable.

The majority of the notified polymer is expected to be cured into an inert matrix as part of its normal use pattern as a primer coating. The notified polymer is irreversibly bound into the matrix and, in this form, is not expected to be bioavailable or biodegradable. Notified polymer in solid waste disposed of to landfill, or in primer coating spilt to the ground during application, is not expected to be mobile and will slowly degrade *in situ*, primarily by abiotic processes. The notified polymer will eventually degrade in landfill, or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon and nitrogen.

Significant amounts of notified polymer are not expected to be released to the aquatic environment. In the event that minor amounts of uncured notified polymer are disposed of to sewer from the cleaning of equipment, it is expected that it will be removed from influent by up to 90% through adsorption to sludge during sewage treatment processes (Boethling & Nabholz, 1997). Bioaccumulation of the notified polymer is unlikely due to its high molecular weight and its limited release to surface waters.

7.1.3 Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.2. Environmental effects assessment

No ecotoxicological data on the notified polymer were submitted. However, an algal growth inhibition study report on a product containing < 50% notified polymer was submitted (NOTOX 2010b). Some inhibition of algal growth was observed, but this could not be directly attributable to the notified polymer as other components were present in the test substance. However, polymers without significant ionic functionality are of low concern to the aquatic environment.

7.2.1 Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental risk assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern as a component in an industrial primer coating. The majority of the notified polymer will be disposed to landfill as cured primer. In its cured state the notified polymer is irreversibly bound into the inert primer matrix and is unlikely to leach or be bioavailable. Due to its limited environmental exposure, the risk of the notified polymer to the environment is expected to be low based on its reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited data provided the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

However, based on a structural alert (epoxy groups), there is the potential for adverse health effects.

Human health risk assessment
Under the conditions of the occupational settings described and with adequate controls to reduce exposure, 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 expected 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:
  - Local exhaust ventilation during formulation processes
  - Spray booths during spray coating operations

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:

- Avoid inhalation exposure during spray application
- Avoid skin and eye contact
- Avoid generation of aerosols and mists during handling
- Where applied by spray in outdoor settings, measures should be taken to reduce worker exposure to spray drift

- Spray application of paint containing the notified polymer should be in accordance with the *National Guidance Material for Spray Painting* (NOHSC, 1999)

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during connecting pumping lines to the steel drums, cleaning the mixing tanks and coating application activities:
  - Protective gloves
  - Long-sleeved protective clothing
  - Safety glasses
  - Respiratory protection during spray application

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

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

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

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified 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(2) of the Act; if
  - the function or use of the polymer has changed from a component of industrial primer coatings at < 50% in one part of 2-part epoxy coating, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 100 tonne per year, 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant. Recommendations have been made regarding products containing the notified polymer.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility ≤ 4.3×10^{-3} g/L at 20°C, pH 7

Method	Modification of OECD TG 120 Solution/Extraction Behaviour of Polymers in Water and OECD TG 105 Water Solubility
Remarks	Flask Method. Three samples of the test item (10 g; purity < 80%) in water (1 L; adjusted to pH 7 with 2 drops 0.1 N NaOH) were agitated at 20°C. After 24 hours the samples were filtered, extracted and analysed. Detection was based on the UV-absorbance of the test item. The water solubility of the test item was determined to be 4.3 mg/L and the water extractability was determined to be 0.041% of the original sample weight. As there was no correction for purity, the water solubility of the notified polymer is ≤ 4.3 mg/L.
Test Facility	Investigative Science Incorporated (2008)

Partition Coefficient (n-octanol/water) log Pow = 3.80 at 25°C

Method	OECD TG 117 Partition Coefficient (n-octanol/water)
Remarks	HPLC Method. The partition coefficient of the test item was interpolated from a calibration curve constructed from standards with defined log Pow values (log Pow range: 1.0 – 6.5). The test item eluted as several peaks, with the main peak (76% peak area) eluting at a time corresponding to a log Pow of 3.76 and a secondary peak (5.7% peak area) corresponding to a log Pow of 4.43, giving a weighted average log Pow of 3.80. All other peaks less than 5% of the total area were not included in the weighted average. The high log Pow indicates that the notified polymer will partition from water to the octanol phase.
Test Facility	Investigative Science Incorporated (2008)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified Polymer

METHOD
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: Ethanol:water (50:50)
- Remarks - Method: The test substance was heated before emulsification in the ethanol/water (temperature not stated).

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 F	2000	0
2	3 F	2000	0

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: No effects of toxicity or mortalities were observed post dosing or during the 14-day observation period in any of the 6 animals.
- Effects in Organs: No gross pathological findings were observed in any rat at necropsy.
- Remarks - Results: All animals gained body weight by day 7 and at the end of the 14-day observation period.

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

TEST FACILITY: Investigative Science Incorporated (2008)

B.2. Irritation – skin

TEST SUBSTANCE: Beckopox EP386w/52WA (containing the notified polymer at < 50%)

METHOD
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 1 M, 2 F
- Vehicle: None
- Observation Period: 72 hours
- Type of Dressing: Semi-occlusive.
- Remarks - Method: No deviations from the protocol.

RESULTS: There was no erythema or edema noted at any observation period.
There were no abnormal physical signs noted during the observation period.
All body weight changes were normal.

CONCLUSION: The test substance is non-irritating to the skin.

TEST FACILITY: MB Research Laboratories (2008)

B.3. Irritation – eye

TEST SUBSTANCE: Beckopox EP386w/52WA (containing the notified polymer at < 50%)

METHOD
- Species/Strain: Rabbit/New Zealand White

Number of Animals	2M, 1 F
Observation Period	72 hours
Remarks - Method	No deviations from the protocol. Fluorescein examination was carried out at 24 h.

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	0	0.3	0	1	< 48 hours	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	2 (1 hour)	< 24 hours	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results	There was no corneal opacity or iritis noted at any observation period. Conjunctival irritation, noted in 3/3 eyes, cleared by 48 hours. There were no abnormal physical signs noted during the observation period.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY MB Research Laboratories (2009)

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