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

**FULL PUBLIC REPORT**

**Base polymer in EPIKURE 8537-WY-60**

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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**FULL PUBLIC REPORT****Base polymer in EPIKURE 8537-WY-60****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT(S)

Chemiplas Australia Pty Ltd (ABN 29 003 056 808)  
3/112 Wellington Parade  
EAST MELBOURNE VIC 3002

## 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/residual monomers, Import volume, Confidential details of use, Polymer constituents and Analogue details.

## VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

Vapour pressure, Adsorption/desorption, Particle size and Flammability limits.

## PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

## NOTIFICATION IN OTHER COUNTRIES

None

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

Base polymer in EPIKURE Curing Agent 8537-WY-60

## OTHER NAME(S)

Polyethylene/polyamide adduct (Generic name listed on MSDS)

## MOLECULAR WEIGHT

$M_n > 1000$  Da

## ANALYTICAL DATA

Reference IR and Field Desorption Mass spectra were provided.

**3. COMPOSITION**

DEGREE OF PURITY      ~ 95%

#### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Clear, amber, very viscous liquid.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< 25°C	Liquid at ambient temperatures.
Boiling Point	Decomposes before boiling	Measured
Density	1099 kg/m <sup>3</sup> at 23°C	Measured
Vapour Pressure	Not determined	Expected to have a low vapour pressure based on high molecular weight.
Water Solubility	0.46 g/L	Measured. Flask method used. The notified polymer contains a significant fraction of hydrophilic moieties. The dissolved part may mainly correspond to the low molecular fraction of the notified polymer.
Hydrolysis as a Function of pH	t <sub>1/2</sub> > 1 year at pH 4, 7 and 9.	Measured. The notified polymer is expected to be hydrolytically stable.
Partition Coefficient (n-octanol/water)	log Pow = 1.25 at 23°C	Measured. The tested result is consistent with the structure of the polymer containing a significant amount of hydrophilic moieties.
Adsorption/Desorption	Not determined	The moderate water solubility and low Pow indicate a low adsorption to soil from water. However, the presence of potentially ionised amine groups may impart the notified polymer a high adsorption to soil.
Dissociation Constant	pKa = 3.3-10	Estimated based on a literature for the relevant raw material. The notified polymer is expected to be ionised in the environmental pH range of 4-9.
Particle Size	Not determined	Liquid at ambient temperatures.
Flash Point	224°C(closed cup) 237°C (open cup)	Measured
Flammability	Not determined	Not expected to be highly flammable based on measured flash point.
Autoignition Temperature	380°C	Measured
Explosive Properties	Not expected to be explosive	The structural formula contains no explosives.

#### 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 storage and handling conditions.

#### 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 (at up to 60%) of EPIKURE 8537-WY-60. It will not be manufactured in Australia.

## 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>	10-30	30-100	30-100	30-100	< 300

## PORT OF ENTRY

Melbourne, Sydney, Brisbane, Adelaide and Perth.

## TRANSPORTATION AND PACKAGING

The notified polymer will be imported as a component (at up to 60%) of EPIKURE 8537-WY-60 in 200 L steel drums and transported by road and rail to end-use sites.

## USE

The notified polymer will be used as a component of a curing agent for water based epoxy paints/coatings for industrial architectural and marine uses.

## OPERATION DESCRIPTION

The imported product EPIKURE 8537-WY-60 containing up to 60% notified polymer will undergo manual formulation with pigments and other ingredients under natural ventilation at the end-use site in a drum or spray container to give the Part B curing agent of a two-pack epoxy-coating system. Part B will contain < 45% of the notified polymer. Part B will then be mixed with Part A to give the finished coating containing < 15% of the notified polymer.

The finished coatings will be applied by professional applicators in industrial and residential settings by spray, brush or roller. Residual coating will be washed manually from the application equipment using recycled paint solvent. For marine use, the paint will be applied to the hull of boats in dry docks.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1 Exposure assessment

#### 6.1.1 Occupational exposure

##### NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transportation	10	1-2	40-50
Application	200	5	20
Maintenance	100	1-2	20

## EXPOSURE DETAILS

##### *Transport*

Exposure to the notified polymer (at up to 60%) during transport is not expected except in the unlikely event of an accident where the drums are breached.

##### *End-use*

Dermal and ocular exposure to the notified polymer (at up to 60%) may occur during manual formulation to give Part B and when mixing with Part A to give the final finished coating product containing the notified polymer at < 15%.

Dermal and ocular exposure of workers to the notified polymer (at < 15%) may occur during application of the finished coating by brush, roller and spray, and when cleaning up application equipment. Inhalation exposure to the notified polymer (at < 15%) is also likely during spray application given only natural ventilation is available at the end-use sites.

In all operations, workers are expected to wear as a minimum gloves, goggles and coveralls to minimise potential for exposure. Organic vapour respirators will be available for use and will be expected to be worn by application workers during spray application.

### 6.1.2. Public exposure

The products containing the notified polymer are for use by industrial workers only and are not intended for DIY use. The public may come into contact with surfaces coated with products containing the notified polymer. Once dried and cured the notified polymer will be contained within the polymer matrix and will not be bioavailable.

### 6.2. Human health effects assessment

The results from toxicological investigations conducted on the products containing the notified polymer (at 60%) and an acceptable analogue of the notified polymer (at 35%) are summarised in the table below. Details of these studies can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity ( <i>analogue at 35%</i> )	LD50 2000 mg/kg bw; harmful
Rabbit, eye irritation ( <i>notified polymer at 60%</i> )	severely irritating
Rabbit, skin irritation ( <i>analogue at 35%</i> )	slightly irritating

#### *Toxicokinetics, metabolism and distribution.*

Given the notified polymer contains a high percent of low molecular weight species (< 1000 Da), absorption across biological membranes may occur. This is supported by the observation of acute oral toxicity in a study conducted on rats (see below). In addition given the favourable water solubility and log Pow values, dermal absorption of the low molecular weight species may also occur. Given the expected low vapour pressure of the notified polymer, it is not expected to present as an inhalation hazard except where mists or aerosols may be formed.

#### *Acute toxicity.*

In an acute oral toxicity study conducted on rats with a product containing an acceptable analogue of the notified polymer at a concentration of 35%, 3 out of 8 animals tested died when dosed at 2000 mg/kg bw/day. No mortalities or signs of toxicity were observed in animals dosed at 175 and 500 mg/kg bw/day. The LD50 for the product was determined to be 2000 mg/kg bw/day (equivalent to 700 mg/kg bw/day for the analogue). Given the other ingredients in the product are unlikely to contribute to the toxicity, the acceptable analogue of the notified polymer is considered to be at least harmful by the oral route. These acute effects are likely to be due to the presence of a high concentration of low molecular weight species (< 1000 Da) in the analogue polymer. As the notified polymer also contains a high concentration of similar low molecular weight species, the notified polymer is expected to be at least harmful by the oral route.

No data was available on the acute dermal or inhalation toxicity. However, given that absorption of the low molecular weight species may occur the potential for acute toxicity via these routes can not be ruled out.

#### *Irritation and Sensitisation*

In a study conducted on one rabbit, the product containing the notified polymer at a concentration of 60% was found to be severely irritating to the eye. Due to severe irritation of the conjunctival tissue, examination of the cornea and iris was obstructed by swelling of the eyelids and a large amount of ocular discharge. For ethical reasons, after 24 hours the study was terminated and the animal sacrificed. After sacrifice the cornea was exposed by dissection. Up to one quarter of the cornea was found to be opaque, while the remaining area was nacreous with no details of the iris visible and the size of the pupil barely discernible. Although the other ingredients present in the product have potential for irritation and corrosion, their concentrations are below the cut-offs for classification of the product and therefore are not expected to contribute significantly to the irritation effects observed. In addition, the result of this study is consistent with the high content of secondary amines along the polymer backbone together with the high percentage of low molecular weight species (< 1000 Da); structural features that may predict corrosion (Hulzebos, 2005). However, only slight skin irritation was observed when a product containing an acceptable analogue of the notified polymer at a concentration of 35% was tested on rabbits. Only very slight erythema was observed for up to 24 hours. Based on the result of this study, the notified polymer is therefore likely to present as a slight skin irritant.

As the vapour pressure of the notified polymer is low, it is not expected to pose an inhalation hazard. However, under conditions where mists can be formed it may present itself as an upper respiratory tract irritant.

Given the notified polymer contains 1,2-diamines along the polymer backbone, a structural alert for sensitisation (Barrett, 1994), the notified polymer may also present as a sensitiser, particularly considering the high percent of

low molecular weight species. Furthermore, the notified polymer contains impurities that are potentially sensitising that may be present above the cut-off level ( $\geq 1\%$ ) in the imported product.

### **Health hazard classification**

Based on the results of the eye irritation study and the acute oral toxicity study conducted on an acceptable analogue, the notified polymer is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

R22: Harmful if swallowed

R41: Risk of serious damage to eyes

## **6.3. Human health risk characterisation**

### **6.3.1. Occupational health and safety**

The notified polymer is classified as a severe eye irritant and harmful by the oral route. In addition, the notified polymer is a slight skin irritant and based on structural alerts is considered as a potential sensitiser. Based on the expected absorption of the low molecular weight species, the polymer may also display acute toxicity via the dermal and inhalation routes. Given the concentration of the notified polymer during its lifecycle in Australia will be above the stated cut-off level for irritation ( $\geq 5\%$ ) and sensitisation ( $\geq 1\%$ ), all workers where exposure may occur are at potential risk from irritation, sensitisation and systemic toxicity, when handling the notified polymer as introduced and in finished coating products. The use of safety goggles, impermeable gloves and coveralls, and the provision of emergency eye wash facilities at all sites where exposure may occur, should reduce these risks.

Inhalation exposure to aerosols of coatings containing the notified polymer (at  $< 15\%$ ) during spray application may lead to irritation of the respiratory tract. Therefore, spray application workers should also wear respirators to ensure the risk is minimised.

Overall, provided that all workers wear the proposed personal protective equipment (safety glasses, protective gloves, coveralls and respirators where appropriate) to limit exposure and follow the safe work practices as stated in the MSDS, the risk to workers, presented by the notified polymer is not considered to be unacceptable.

### **6.3.2. Public health**

Based on the negligible exposure, the risk to the health of the public by the notified polymer is not considered to be unacceptable under normal use conditions.

## **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 or formulated in Australia. It will be imported as a constituent of a polymer solution at up to 60% in 200L steel drums.

##### **RELEASE OF CHEMICAL FROM USE**

At the end use site, the solution containing the notified polymer will be mixed into a coating product consisting of a Part B curing agent and a Part A epoxy resin. Once mixed, the notified polymer is designed to react with the Part A epoxy to harden to a solid mass. Release of the notified polymer from mixing is expected from accidental spill only.

During application, the maximum amount of lost due to overspray is 30%. For marine applications the coating is expected to take place outdoors under non-windy conditions. Any possible overspray will be collected and disposed of to landfill. For architectural applications the notified polymer will be applied in an industrial environment or in residential or commercial areas. Wherever possible overspray will be collected by protective sheeting on surrounding surfaces and disposed of to landfill. Release from equipment cleaning is expected to be  $< 1\%$  and will be most likely disposed of to landfill. Cleaning of equipment in a residential or commercial area is likely to lead into sewage. As a worst case scenario it is expected that 10% of the release from cleaning

will remain unreacted. This suggests that 0.05% of the unreacted notified polymer will be released to sewage with an assumption that 50% of the coating will be used in residential and commercial areas. The reacted notified polymer will become part of the non-hazardous inert solid resin and any release can be sent to landfill.

#### RELEASE OF CHEMICAL FROM DISPOSAL

Approximately 1% of the notified polymer is expected to remain in the steel drum. The empty drums will be sent to a licensed waste disposal company or recycled, where the notified polymer will be thermally decomposed into water and oxides of carbon and nitrogen.

### 7.1.2 Environmental fate

No environmental fate data has been submitted. The notified polymer is not expected to be readily biodegradable based on the molecular structure. Neither is it expected to have potential for bioaccumulation due to the high molecular weight.

The majority of the notified polymer will be associated to substrates via coating application. For marine application, losses of the notified polymer occurring from removal after service periods and during application will be collected in the discharge bunding of the slipways and dry docks involved. For architectural use the notified polymer applied will be sent to landfill together with the substrates at the end of their useful life. In either way, the notified polymer will undergo slow processes of biotic and abiotic degradation, forming small molecules of water and oxides of carbon and nitrogen.

### 7.1.3 Predicted Environmental Concentration (PEC)

The PEC has not been calculated due to the very limited release to the water environment expected from the reported use pattern.

## 7.2. Environmental effects assessment

No ecotoxicity data were submitted. The presence of potential cationic moieties may have toxicity to the aquatic life. However, this is not considered to be a concern given the limited release to water environment due to the proposed use pattern.

### 7.2.1 Predicted No-Effect Concentration

The PNEC can not be calculated since no ecotoxicity data for the notified polymer is available.

## 7.3. Environmental risk assessment

The Risk Quotient (PEC/PNEC) has not been calculated since neither PEC nor PNEC has been calculated. The notified polymer is not expected to pose an unacceptable risk to the aquatic environment based on its limited aquatic release resulting from the reported use pattern.

## 8. CONCLUSIONS AND REGULATORY OBLIGATIONS

### Hazard classification

Based on the available data the notified polymer is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

- R41 Risk of serious damage to eyes
- R22 Harmful if swallowed

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	<i>Hazard category</i>	<i>Hazard statement</i>
<b>Health</b>		



Eye irritation	1	Causes severe eye damage
Acute (oral)	4	Harmful if swallowed

### 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

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

### Recommendations

#### REGULATORY CONTROLS

##### Hazard Classification and Labelling

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - R41 Risk of serious eye damage
  - R22 Harmful if swallowed

Xn; R22 R41

Conc ≥ 25%: Xn; R22 ; R41

≥ 10%Conc < 25%: Xi; R41

≥ 5%Conc < 10%: Xi; R36

##### Health Surveillance

- As the notified polymer is a potential skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

#### CONTROL MEASURES

##### Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced and in the final coating products:
  - Avoid skin and eye contact
  - Avoid inhalation of vapours, mists and aerosols
  - A shower station should be available
  - Provision of emergency eye wash facilities
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced and in the final coating products:
  - Coveralls
  - Safety goggles
  - Impermeable gloves
  - Organic vapour respirators (as needed)

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 chemical 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(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1000;or
- (2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a curing agent for epoxy-based coatings or is likely to change significantly;
  - the amount of chemical being introduced has increased from 300 tonnes per annum, or is likely to increase, significantly;
  - 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 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.

**APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES****Density** 1099 kg/m<sup>3</sup> at 23°C

Method ASTM D792 - Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement  
 Test Facility Polyhedron Laboratories (2006a)

**Water Solubility** 0.46 g/L

Method OECD TG 105 Water Solubility.  
 Remarks Flask Method. Concentrations were determined by ultraviolet spectroscopy at 270 nm. The concentration of notified polymer in test aqueous phase increased from 0.203 g/L at the first day to 0.46 g/L at the third day. The notified polymer consists of significant amount of hydrophilic moieties which may contribute to the moderate water solubility. Considering the notified polymer contains a high percentage of low molecular weight species (< 1000 Da), the tested solubility may correspond to this part of the notified polymer.  
 Test Facility Polyhedron Laboratories (2005a)

**Hydrolysis as a Function of pH**

Method OECD TG 111 Hydrolysis as a Function of pH.

<i>pH</i>	<i>T</i> (°C)	<i>t</i> <sub>1/2</sub>
4	50	> 1 year
7	50	> 1 year
9	50	> 1 year

Remarks UV-visible far IR spectrophotometer was used to detect the expected product from hydrolysis. Test solutions were placed into a constant temperature circulating bath at 50°C in the dark for 7, 10 and 17 days for the pH 4, 7 and 9, respectively. No hydrolysis product was detected, indicating the notified polymer is hydrolytically stable in water in the pH range of 4-9.  
 Test Facility Polyhedron Laboratories (2006b)

**Partition Coefficient (n-octanol/water)** log Pow = 1.25 at 23°C

Method OECD TG 117 Partition Coefficient (n-octanol/water)  
 Remarks Flask Method. Ultraviolet spectroscopy was used for concentration determination. Test was conducted in duplicates at octanol/water ratios of 50/50, 50/25 and 25/50.  
 Test Facility Polyhedron Laboratories (2006c)

**Flash Point** 224°C(closed cup); 237°C (open cup)

Method ASTM D93 - Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester.  
 ASTM D92 - Standard Test Method for Flash and Fire Points by Cleveland Open Cup Tester  
 Test Facility Polyhedron Laboratories (2006a)

**Autoignition Temperature** 380°C

Method ASTM D1929 - Standard Test Method for Determining Ignition Temperature of Plastics  
 Test Facility Polyhedron Laboratories (2006a)

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

TEST SUBSTANCE	Product containing acceptable analogue of notified polymer at 35%.
METHOD	US EPA OPPTS 870.1100.
Species/Strain	Rat/Sprague-Dawley
Vehicle	None
Remarks - Method	No significant protocol deviations. Similar to OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.

## RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	1F	175	0/1
2	4F	550	0/4
3	8F	2000	3/8
4	1F	5000	1/1

LD50  
Signs of Toxicity

2000 mg/kg bw  
In the initial limit test of 5000 mg/kg bw/day the one animal tested died on the day of dosing. Prior to death activity decrease, convulsions and staggered gait were observed. There were no mortalities observed in the 175 and 550 mg/kg bw/day during the course of the study. However, 3 animals out of 8 tested died on the day of dosing when dosed with 2000 mg/kg bw/day.

Slight piloerection was observed in one test animal of the 550 mg/kg bw/day dose group on Day 1. Matted fur and moderate piloerection was observed on Days 9 and 10 for one animal in the 2000 mg/kg bw/day dose group that survived the course of the study.

Effects in Organs

Body weight gains in all surviving animals was unaffected by the test substance.  
The gross necropsy on animals that died on test revealed for the 2000 mg/kg bw/day dose group crusted fur and discoloured lungs, liver and contents of the gastrointestinal tract. Empty stomach and intestines was revealed for the animal dosed at 5000 mg/kg bw/day. The gross necropsy on animals surviving to termination of the study revealed no observable abnormalities.

Remarks - Results

The LD50 for the product containing the analogue polymer at 35% is estimated to be 2000 mg/kg bw/day.

CONCLUSION

The product containing the acceptable analogue of the notified polymer at 35% is harmful via the oral route.

TEST FACILITY

Stillmeadow Inc. (2004a)

**B.2. Irritation – eye**

TEST SUBSTANCE	EPIKURE 8537-WY-60 (product containing 60% notified polymer)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	One
Observation Period	24 hours
Remarks - Method	No significant protocol deviations.

## RESULTS

<i>Lesion</i>	<i>Observation period (hrs)</i>	
	1	24
<i>Conjunctiva: redness</i>	2	3
<i>Conjunctiva: chemosis</i>	3	4
<i>Conjunctiva: discharge</i>	3	3
<i>Corneal opacity*</i>	-	3/4**
<i>Iridial inflammation*</i>	-	-

\*Cornea and iris could not be scored due to swelling of the eyelids and a large amount of discharge.

\*\*After sacrifice and exposing cornea by dissection.

Remarks - Results	Severe effects on the cornea and conjunctivae were observed at the 1 and 24-hour observation periods. Examination of the corneal injury and iridic irritation was impossible due to swelling of the eyelids and large amount of discharge. Signs of necrosis of the eyelids and nictitating membrane were observed at the 24-hour observation period. For ethical reasons, after 24 hours the study was terminated and the animal sacrificed. After sacrifice the cornea was exposed by dissection. Up to one quarter of the cornea was found to be opaque, while the remaining area was nacreous with no details of the iris visible and the size of the pupil barely discernible.
CONCLUSION	The product containing the notified polymer at 60% is severely irritating to the eye.
TEST FACILITY	NOTOX (1998a)

**B.3. Irritation – skin**

TEST SUBSTANCE	Product containing acceptable analogue of notified polymer at 35%
METHOD	US EPA OPPTS 870.2500
Species/Strain	Rabbit/New Zealand White
Number of Animals	Three
Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.

## RESULTS

Lesion	Mean Score*			Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3			
Erythema/Eschar	0.33	0.33	0.33	1	< 48 hrs	0
Oedema	0	00	0	0	N/A	0

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

Remarks - Results	Very slight erythema was observed in all animals at the 1-hour and 24-hour observation period. No signs of erythema were observed at the 48-hour observation period. Oedema was not observed at any time throughout the study.
CONCLUSION	The product containing the acceptable analogue of the notified polymer at 35% is slightly irritating to the skin.
TEST FACILITY	Stillmeadows Inc (2004b)

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