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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in RE-89-8919

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)
PPG Industries Australia Pty Ltd (ABN 82 055 500 939)
McNaughton Road
Clayton VIC 3168

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details, manufacture/import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: melting/boiling point, density, vapour pressure, water solubility, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, flash point, flammability, autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
RE-89-8919 (containing < 30% notified polymer)

OTHER NAME(S)
Polyester-modified epoxy

ANALYTICAL DATA
A reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY > 70%

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

ADDITIVES/ADJUVANTS None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Stable under normal conditions of use

DEGRADATION PRODUCTS
Stable under normal conditions of use

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Viscous liquid

Property	Value	Data Source/Justification
Boiling Point	Not determined > 37.8 °C for imported product*	MSDS. Boiling point of the notified polymer in isolation is expected to be higher than this, given its high molecular weight and relatively low content in the imported product (< 30%).
Density	1200 kg/m^3 for imported product*	MSDS
Vapour Pressure	< 1.3 x 10^{-9} kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2007)
Water Solubility	Not determined	The notified polymer is expected to have very low water solubility based on structural considerations.
Hydrolysis as a Function of pH	Not determined	The notified polymer is expected to hydrolyse at environmental pH (4 – 9)
Partition Coefficient (n-octanol/water)	Not determined	Based on its expected low water solubility the notified polymer is anticipated to partition to the octanol phase
Adsorption/Desorption	Not determined	Based on its expected low water solubility the notified polymer is anticipated to adsorb to soil and sediment and therefore be immobile in soil
Dissociation Constant	Not determined	The notified polymer has no dissociable functions
Particle Size	Not determined	Notified polymer is a viscous liquid at room temperature.
Flash Point	147°C	MSDS
Flammability	Not determined	The notifier has stated that the notified polymer is not expected to be flammable based on experience in use.
Autoignition Temperature	Not determined	The notifier has stated that the notified polymer is not expected to autoignite based on experience in use.
Explosive Properties	Not determined	The notified polymer contains known explosophores, however, the notifier has stated that it is not expected to have explosive properties.

* The notified polymer will not be isolated during its life cycle in Australia.

DISCUSSION OF PROPERTIES

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

Reactivity

The notifier has stated that the notified polymer is stable under normal conditions, however, it will hydrolyse at environmental pH.

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 into Australia (< 30%) as a component of a two-pack coating system.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 12	< 12	< 20	< 25	< 30

PORT OF ENTRY
Melbourne, Sydney, Brisbane

IDENTITY OF RECIPIENTS
PPG Industries Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The product containing the notified polymer will be transported from the port by road, rail or sea to the notifier's warehouse in sealed 200 kg drums.

USE
The notified polymer is a component (< 30%) of a two-pack system for the coating of large sea vessels and onshore and offshore metal structures.

OPERATION DESCRIPTION
At the end use sites, the base part of the coating system (containing the notified polymer at < 30%) will be mixed with the hardener part of the coating system and other additives. This will involve manual transfer and mixing may be performed manually or using a power stirrer (in an open container). The resulting mixture (< 18% notified polymer) will then be manually transferred to the spray equipment and subsequently sprayed onto the metal substrate using airless spray equipment or be spread onto the equipment using a trowel (hand tool). This may be performed in factory settings or at the sites of previously constructed structures. The majority of coated substrates (including those designed for off-shore use) will be overcoated with a different layer.

At the end of the operational life of the metal substrate coated with the notified polymer, the notified polymer may be removed by abrasive blasting or hydroblasting.

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	6 - 8	2 - 3	10 - 15
Mixing and application	50	8	260

EXPOSURE DETAILS
Workers involved in transport, storage and distribution of the imported notified polymer may be exposed to the notified polymer in the case of an accident where packaging is breached.

Dermal and ocular exposure of workers to the notified polymer may occur during the transfer and mixing of the coating (< 30% notified polymer), subsequent manual transfer to the spray equipment (< 18% notified polymer), the spray or trowel application of the coating (< 18% notified polymer) to the substrate, and the manual decanting and cleaning of equipment (< 18% notified polymer). It is expected that such exposure may be reduced by workers performing these tasks in well-ventilated areas and wearing personal protective equipment, including eye protection, coveralls and gloves.

Inhalation exposure of workers to the notified polymer (up to 18%) may occur during spraying. Such exposure is expected to be lowered by performing the tasks in well ventilated areas, by the use of appropriate respirators, and by the viscous nature of the coating.

It is also noted that, due to the presence of hazardous substances in the product containing the notified polymer, there are expected to be controls in place during its handling that are appropriate for these hazards. As such, these controls are expected to correspondingly reduce exposure of workers to the notified polymer also.

Workers may make dermal contact with the notified polymer once the coating formulation is dried to the substrate. However, the notified polymer is not expected to be bioavailable from the dried and cured coating as it will be immobilised within a film. In addition, in most circumstances the coating may be overcoated with another layer and thus exposure is not likely to occur.

At the completion of the useful life of substrates coated with the notified polymer, workers involved in the removal of the coating by abrasive blasting or hydroblasting may experience inhalation exposure to the cured form of the notified polymer. During such processes, workers may use personal protective equipment in order to lower exposure.

6.1.2. Public exposure

Public exposure to the notified polymer is not expected during transport or distribution, except in the event of spills.

The notified polymer is for industrial use only and therefore the public is not expected to be exposed. If the public were to come into contact with the structures coated with the notified polymer, it will not be bioavailable as it will be reacted into the coating matrix. In addition, in most cases the coating will be covered with another coating and thus public exposure would not occur.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Mice, sensory irritation - inhalation	RD50 = 1751.6 mg/m^3
Rabbit, skin irritation	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 relatively low. However, the polymer contains some species with NAMW < 1000 Da and results of the acute dermal toxicity suggest that some of the notified polymer is absorbed dermally.

Acute toxicity
The notified polymer is of low acute toxicity *via* the dermal route with no mortalities observed during the study. However, some signs indicative of systemic toxicity occurred during this study.

No acute oral or inhalation toxicity studies were provided for the notified polymer.

Sensory irritation - inhalation
A test was performed on the notified polymer involving exposure of mice to liquid aerosols of the notified polymer with acetone. Animals were exposed to several concentrations of test substance and reductions in respiratory rate were monitored. The concentration at which the respiration rate had decreased to 50% compared to the control was determined to be 1751.6 mg/m^3. The results indicate that the notified polymer causes sensory irritation of the respiratory tract when aerosolised with acetone.

Irritation and sensitisation
The notified polymer was slightly irritating to the skin based on the supplied rabbit study according to OECD test protocols. More severe irritation was seen after the 24 hour dermal exposure period in the dermal toxicity

study at 2000 mg/kg bw.

No information was supplied on the skin sensitisation or eye irritation potential of 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) are known to have a higher sensitising potential compared with oligomers of higher molecular weight (HSE, 2003). The potential of the notified polymer to cause sensitisation would be reduced due to its relatively low proportion of species with molecular weight < 500 Da and < 1000 Da.

Mutagenicity, carcinogenicity and toxicity for reproduction
No genotoxicity or carcinogenicity studies on the notified polymer were provided. 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 specifies that structures with epoxy equivalent weights of > 1,000 Da are presumed not to pose a hazard under any conditions. In addition, it indicates that concerns are confined to species with molecular weights < 1000 Da. The functional group equivalent weight of the notified polymer is calculated to be approximately 430 Da, however, its molecular weight (> 1,000 Da) and relatively low proportion of species with molecular weight < 1000 should mitigate the health concerns of the notified polymer associated with this functional group.

Health hazard classification
Based on the limited information provided, the notified polymer is not classified as hazardous for dermal toxicity and skin irritation according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). Data on other health end points were not provided.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Limited toxicological data was supplied for the notified polymer. The notified polymer is expected to be slightly irritating to the skin and may cause irritation of the respiratory tract upon inhalation. The risk of skin or respiratory sensitisation, or other adverse effects cannot be ruled out, though are expected to be reduced by the low proportion of low molecular weight species.

There is a possibility of ocular and dermal exposure to the notified polymer at < 30% during transfer and mixing operations and < 18% during subsequent transfers and handling, the cleaning of mixing tanks and application of the coating by spray or trowel. However, the expected use of PPE by workers and adequate ventilation of work areas should minimise exposure during these activities.

Inhalation (aerosol) exposure of workers to the notified polymer (< 18%) may occur during spray operations. The size distribution of workplace aerosols is expected to be relatively broad and to encompass the inhalable size (Oller 2010). At such sizes, irritation of the respiratory tract may occur. However, the use of suitable and correctly fitted respiratory equipment is expected to lower inhalation exposure, as well as performing spray operations in well-ventilated areas.

The measures in place to minimise risks involved in handling the hazardous substances present in the product containing the notified polymer are expected to correspondingly reduce the risk associated with handling of the notified polymer.

Inhalation exposure of workers during blasting of surfaces coated with the notified polymer may cause respiratory irritation, however, the use of appropriate PPE should lower the potential exposure.

Overall, provided workers wear appropriate PPE, including correctly fitted respiratory equipment during spray operations, the risk to the health of workers 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 not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured or reformulated in Australia. The release of the notified polymer to the environment during importation, storage, and transport is unlikely. The most likely source of a release to the environment during these activities will be a transport accident. However, the capacity and specifications of the import containers are likely to minimise the extent of any such releases. Releases that do occur as a result of accidents are expected to be physically contained, absorbed on inert material, and either reused or sent for safe disposal to landfill.

RELEASE OF CHEMICAL FROM USE

During industrial use of the notified polymer (mixing and transferring), it is estimated that < 1% of the notified polymer will be spilt. These spills will be contained and disposed to landfill. Less than 1% of the notified polymer may remain as residues in the product containers which will be disposed to landfill.

The product containing the notified polymer will be used to coat onshore and offshore metal structures. The offshore structures will be in contact with seawater, however, in these circumstances, the coating containing the notified polymer will be overcoated with appropriate coatings preventing the notified polymer coming into contact with the aquatic environment. During application by spray, it is expected that 80 – 90% of coating will be transferred to end-use articles and the remaining 10 – 20% will form overspray that will be collected on tarpaulins or plastic coverings which are expected to be disposed to landfill. As the coating is of high viscosity the material is applied in droplets and is not atomised to fine particles. Some coating will also be applied by hand using trowels.

Equipment used to apply the coating formulations may be rinsed with water. It is estimated that 1% of notified polymer may be released to sewer treatment plants due to application equipment rinsing. These washings will undergo a treatment during which time the notified polymer will be removed and disposed to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the notified polymer left in empty storage containers from coating use will ultimately be disposed of to landfill. However, some containers may be recycled and a small amount of notified polymer (< 1%) may be released to onsite sewage treatment where it will be treated, removed and disposed of to landfill. The notified polymer will be irreversibly combined with other chemical substances as part of the coating process. In the case of coating applications, the notified polymer will be immobilised within a polymeric film on coated articles.

The cured coating is expected to remain in place on coated structures for their operational life (typically 25 years) unless damaged. The notified polymer incorporated in this coating will ultimately either be removed by abrasive blasting and hydroblasting or disposed of along with the surfaces which will either go to metal recyclers or be disposed of to landfill. Abrasively removed coating will be collected and disposed of to landfill. During metal recycling, the coating matrix will be destroyed via thermal decomposition, generating water and oxides of carbon.

7.1.2 Environmental fate

No environmental fate data were submitted. Most of the notified polymer (> 98%) is expected to be cured into a solid polymer matrix as part of its normal use pattern and is not therefore expected to be bioavailable or biodegradable. The majority of the imported quantity of notified polymer is expected to be thermally decomposed during recycling of metal structures to which it is applied. Bioaccumulation of the uncured polymer is unlikely due to its high molecular weight and limited potential for aquatic exposure. Notified polymer, both in the uncured and cured forms, disposed of to landfill is not expected to be mobile and it will slowly degrade by abiotic and biotic processes to produce water and oxides of carbon.

7.1.3 Predicted Environmental Concentration (PEC)

The notified polymer is not expected to be present at significant concentrations in the aquatic environment because of its anticipated low water solubility and very low potential for direct release to surface waters when used in surface coatings. A PEC has therefore not been calculated.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. The notified polymer has functionality known to be toxic to aquatic life. However, no significant exposure of the notified polymer to aquatic organisms is expected. Furthermore, the majority of the notified polymer will be irreversibly combined with other chemical substances as part of the coating process and not be bioavailable.

7.2.1 Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) was not calculated as no ecotoxicological data were submitted and there will be very low potential for aquatic exposure.

7.3. Environmental risk assessment

A Risk Quotient is unable to be quantified as a PEC and PNEC were not calculated. The reported use pattern of the notified polymer indicates that there is no significant anticipated aquatic release. Moreover, after curing, the majority of the imported quantity of notified polymer will be reacted irreversibly with other chemicals and not be bioavailable nor biodegradable. The coating containing the notified polymer will be an undercoat and therefore will not be directly exposed to the aquatic environment. Hence, the environmental exposure is expected to be minimal. On the basis of the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the limited information provided, the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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:
  - Use under well-ventilated conditions

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid contact with eyes and skin
  - Avoid inhalation of aerosols during spray application
  - 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 mixing operations (< 30%):
  - Safety glasses
  - Gloves
  - Overalls

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during spray application (< 18%):
  - Suitable respiratory protection
  - Safety glasses
  - Gloves
  - Overalls

  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(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 polymer has changed from component of an industrial coating system at < 30% for large sea vessels and onshore and offshore metal structures, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 30 tonnes per annum, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - the method of manufacture of the polymer in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect of the polymer on occupational health and safety, public health, or the environment;

- 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 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 B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	Similar to OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rabbit/New Zealand White
Vehicle	None
Type of dressing	Occlusive.
Remarks - Method	No significant protocol deviations.
RESULTS	
LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Skin reactions ranged from very slight to severe erythema and/or eschar and/or petechial haemorrhages with none to slight oedema.
Signs of Toxicity - Systemic	Many animals exhibited faecal and urine stains, unkempt hair coat, lacrimation and soft stool at various observation times throughout the study. There were also a small number of incidences of diarrhoea and mucoid faeces.
Effects in Organs	At necropsy (14 days), three male rabbits had congested/red lungs with haemorrhage and two females had paraovarian cysts at necropsy. Gross lesions were also seen to the skin, trachea and nasal turbinates of one male animal and crusty skin was observed on another three animals.
Remarks - Results	No mortality observed in any of the test animals (5 males, 5 females treated with 2000 mg/kg bw notified polymer). Some animals experienced a reduction in body weight during the observation period, however, they had gained weight by the conclusion of the study.
CONCLUSION	The notified polymer is of low toxicity via the dermal route.
TEST FACILITY	PPG (1989a)

B.2. Sensory Irritation – inhalation

TEST SUBSTANCE	Notified polymer
METHOD	
Species/Strain	Mice/Swiss Webster
Vehicle	Acetone
Method of Exposure	Head-only exposure
Exposure Period	30 minutes
Physical Form	Liquid aerosol
Particle Size	4.2 ± 2.1 μm (Mass Median Aerodynamic Diameter (MMAD))
Remarks - Method	Sensory irritation was measured using reflex inhibition of respiratory rates in mice. Groups of animals were exposed to a series of concentrations of liquid aerosols of the test substance to construct a concentration-response curve to determine the concentration that elicited a 50% decrease in respiratory rate. Gravimetric analysis was used to determine the concentration of the test substance in the test atmosphere. Gas chromatography was used to determine acetone concentrations in the test atmosphere.
RESULTS	

Number and Sex of Animals	*Concentration*		*Respiratory rate decrease (%)*
	Test substance (mg/m^3)	*Acetone (ppm)*	
4 males	118.4	1980.9	1.1
4 males	388.3	6253.8	14.4
4 males	711.1	9894.4	24.6
4 males	824.4	13191.6	49.6
4 males	1862.0	25212.9	44.5
4 males	2261.2	44486.0	59.5

Respiratory decrease of 50% (RD50) 1751.6 mg/m^3
95% confidence interval: 795.5 to 3856.7 mg/m^3
Remarks - Results No mortality was observed during the test.

CONCLUSION The notified polymer caused a decrease in respiratory rate of the test animals under the conditions of the test.

TEST FACILITY PPG (1990)

B.3. Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD Similar to ECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 6 males
Vehicle None
Observation Period 14 days
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.8	2	< 10 days	0
Oedema	0.6	1	< 7 days	0

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

Remarks - Results Skin reactions ranged from none to well defined erythema and / or none to very slight oedema up to the 72 hour observation. All reactions had cleared by day 10.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY PPG (1989b)

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