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July 2015

# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

## **PUBLIC REPORT**

## Polymer 1 in Anti-Terra-250

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

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

This 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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#### **SUMMARY**

The following details will be published in the NICNAS Chemical Gazette:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1833	ResChem	Polymer 1 in Anti-	ND*	< 20 tonnes per	Component of
	Technologies	Terra-250		annum	coatings, sealants,
	Pty Ltd				adhesives and fillers

<sup>\*</sup>ND = not determined

## **CONCLUSIONS AND REGULATORY OBLIGATIONS**

#### Hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004).

## Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

#### **Environmental risk assessment**

On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

#### Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation and end-use applications:
  - Enclosed, automated systems where possible
  - Ventilated spray booths during spray application where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation and end-use:
  - Avoid skin and eye contact
  - Do not inhale aerosols
- A person conducting a business or undertaking at a workplace should ensure that the following personal
  protective equipment is used by workers to minimise occupational exposure to the notified polymer
  during reformulation and end-use:
  - Gloves
  - Protective coveralls
  - Safety glasses
  - Respiratory protection if inhalation exposure may occur

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.
- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of the Classification and Labelling of Chemicals* (GHS) as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

#### Disposal

 Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

## 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 polymer 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 Da;

or

- (2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from component of coatings, sealants, adhesives or fillers, or is likely to change significantly;
  - the amount of polymer being introduced has increased, 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 (M)SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

## **ASSESSMENT DETAILS**

#### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

ResChem Technologies Pty Ltd (ABN: 90 315 656 219)

Suite 1103, 4 Daydream Street,

Warriewood NSW 2102

NOTIFICATION CATEGORY

Limited: Synthetic polymer with  $Mn \ge 1,000$  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, analytical data, polymer constituents, residual monomers/impurities, additives/adjuvants, use details, details of physico-chemical properties and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2001)

China (2011)

Korea (2013)

#### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Anti-Terra 250 (product containing the notified polymer)

CAS NUMBER

Not assigned

MOLECULAR WEIGHT

>1,000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

## 3. COMPOSITION

DEGREE OF PURITY

>97%

**DEGRADATION PRODUCTS** 

No degradation is expected under normal conditions of use.

#### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT  $20\,^{\circ}\text{C}$  AND  $101.3\,\text{kPa}$ : Beige solid substance

Property	Value	Data Source/Justification			
Melting Point/Freezing Point	Not determined	Solid at room temperature			
Boiling Point	Not determined	Solid at room temperature. It is expected to be >200 °C. However, the polymer is expected to degrade below this temperature.			

Density Vapour Pressure	1100 kg/m³ at 20 °C Not determined	MSDS As the notified polymer is a solid at room temperature and has a relatively high molecular weight, the vapour pressure is expected to be low (<0.1 kPa estimated)
Water Solubility	Completely miscible	MSDS
Hydrolysis as a Function of pH	Not determined	Expected to be hydrolytically stable
Partition Coefficient (n-octanol/water)	$\log Pow = < 1$	Estimated based on solubility in water
Adsorption/Desorption	$\log K_{oc} = < 3$	Estimated
Dissociation Constant	Not determined	Expected to dissociate into its constituents
Particle Size	Not determined	The notified polymer will be introduced in an aqueous solution and will not be isolated during any part of its lifecycle.
Flash Point (product)	>100 °C	MSDS
Solid Flammability	Not determined	The polymer will not be isolated from aqueous solution during any part of its lifecycle
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Based on the structure, the notified polymer is not expected to be explosive.
Oxidising Properties	Not determined	Based on the structure, the notified polymer is not expected to have oxidising properties

## Reactivity

The notified polymer is expected to be stable under normal conditions of use.

## Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

#### 5. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years

The notified polymer will be imported into Australia as a component of an aqueous solution at <50% concentration for reformulation into coatings and other industrial products.

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

Year	1	2	3	4	5
Tonnes	<5	<10	<20	<20	<20

PORT OF ENTRY Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

ResChem Technologies Pty Ltd

## TRANSPORTATION AND PACKAGING

The notified polymer will not be manufactured in Australia. It will be imported into Australia as a component of a wetting and dispersing additive at <50% concentration in sealed steel 25 kg or 200 kg drums. The notified polymer will be transported by road or rail to warehouses and storage facilities prior to distribution to end users for reformulation and repackaging into various sized bags.

#### USF

The notified polymer will be used as a wetting and dispersing additive in a range of coating applications such as architectural paints, industrial coatings, protective coating systems, automotive OEM coatings and leather finishes. It will also be used as a wetting and dispersing additive such as for controlled flocculation of aqueous primers, fillers/filler slurries, adhesives and sealants, to prevent sedimentation of fillers and inorganic pigments and enhancing thixotropy.

The final concentration of the notified polymer in the different end-use products will typically be 0.35 - 3.5 % based on the nature of the pigment.

#### OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia. It will be imported into Australia as a component of the product Anti-Terra-250 in 25 or 200 kg drums. The imported product will be stored at the notifier's storage facility before the product is redistributed to end-users and reformulators.

#### Reformulation

At the reformulation site, the product containing the notified polymer will be blended into end-use products. The blending process for the different end-uses will essentially be the same. The notified polymer solution (<50% notified polymer) will be manually weighed or metered directly from the storage drums into a stainless steel blending tank and mixed with pigments and resins to form the millbase. The millbase is then pumped into a mixing vessel to which the remaining additives are added to form the finished product. Mixing, milling and filling operation of the colourants containing the notified polymer is expected to be automated. Samples will be taken for quality control testing by laboratory technicians. The finished product ( $\le 3.5\%$  notified polymer) will be fed into product containers by gravity from the bottom of the mixing vessel tank through a filter and filling lines.

#### End-use

Coating formulations will be manually or mechanically mixed and then poured into trays, containers (size depending on application) or spray guns prior to application. Automotive, general industrial and architectural coatings will be applied by spray (40%), brush (10%) or roller (50%). It is expected that spray applications will be conducted in spray booths at industrial sites.

In leather finishing, application of the product containing the notified polymer may be by spray or a rolling machine. In the latter method, the solution will be stirred and fixation will occur by passing the solution through a pad mangle containing the leather. The leather will then be dried and the process is completed.

Fillers, adhesives and sealants are also likely to be applied to substrates by varying methods, which may include manual application.

Workers will clean coating and leather finishing equipment such as mixing vessels and coating applicators by rinsing them with water and or solvents. The used containers will be disposed of according to existing waste treatment regulations by licensed waste management contractors.

#### 6. HUMAN HEALTH IMPLICATIONS

#### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

#### CATEGORY OF WORKERS

Category of Worker	Number	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Waterside workers	10	4	50
Storage and transport personnel	70	4	150
Manufacture - Blending			

-coating production workers	40	5	200
-quality control Laboratory technicians	10	2	100
Manufacture - Application			
-coatings workers	2	1	20

EXPOSURE DETAILS

*Transport and storage* 

Transport, storage and waterside workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident where the packaging is accidently breached.

#### Reformulation

During reformulation process, operators may be exposed via dermal and ocular routes to the notified polymer (at <50% concentration) such as during weighing the notified polymer and charging it to the mixing vessel. Laboratory technicians taking the samples of the product containing the notified polymer for quality control and operators carrying out the cleaning of mixing tanks and filling lines may also be exposed to the notified polymer during these processes. The workers' main route of exposure to the notified polymer will be dermal and ocular. Exposure is unlikely to occur during mixing, milling and filling the coatings containing the notified polymer due to the automated nature of the operations. As the notified polymer is not expected to be volatile, inhalation exposure is unlikely to occur unless aerosols are generated. Exposure will be minimised by the use of appropriate engineering controls and personal protective equipment (PPE) such as gloves, safety glasses, hard hat and overalls.

#### Coating Applications

Dermal and ocular exposure to the notified polymer (at <3.5%) may occur during mixing, adding the formulated product containing the notified polymer into the dye bath in the leather finishing applications, or during pouring into trays or spray guns for brush, roller and spray applications. Dermal and ocular exposure may also occur during cleaning up the equipment. Exposure will be minimised by the use of appropriate engineering controls and personal protective equipment (PPE) such as gloves, safety glasses, hard hat and coveralls.

Possible inhalation exposure to the notified polymer from spraying may occur. However, exposure will be mitigated by the use of ventilated spray booths. Air respirators will also be worn by workers when necessary.

#### Other end-uses

During end-use in leather finishing, workers may have dermal, ocular or inhalation exposure to the products containing the notified polymer at < 3.5%. The notifier stated that workers are expected to wear protective eye wear or face shields, as well as gloves and overalls. Where spray application occurs, the stated use of a water curtain may reduce inhalation exposure of workers to some extent. Workers applying fillers, adhesives or sealants may have dermal and ocular exposure. Inhalation exposure is only likely to occur if the products are sprayed.

Once the products containing the notified polymer have been applied to substrates and dried, the polymer is expected to be bound in the product matrix, and to not be bioavailable.

## **6.1.2.** Public Exposure

The notified polymer and products containing it will only be for industrial use and not be sold to the general public. However, the general public may be dermally exposed to coated surfaces containing the notified polymer. Once cured, the coated surface containing the notified polymer forms an inert film and the notified polymer will be immobilised and is not expected to be bioavailable.

#### 6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	Result and Assessment Conclusion
Rat, acute oral toxicity (60% solution)	LD50 >2000 mg/kg bw; low toxicity
Rabbit, skin irritation (60% solution)	slightly irritating
Rabbit, eye irritation (60% solution)	slightly irritating

The notified polymer has a high molecular weight (> 1,000 Da). However it contains a relatively high percentage of low molecular weight species < 1,000 Da; hence possible absorption across biological membranes may occur. It is surface active and potentially cationic, and contains a functional group which is a structural alert for corrosion and sensitisation.

Only limited toxicity data were submitted. A 60% solution of the notified polymer was of low acute oral toxicity to rats (LD50>2000 mg/kg bw) and a slight skin and eye irritant in studies on rabbits.

#### Health hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

#### 6.3. Human Health Risk Characterisation

#### 6.3.1. Occupational Health and Safety

Based on structural alerts and available toxicological information, the notified polymer is a slight irritant and has sensitisation potential. The risk of irritation would be reduced as the polymer is imported at <50% and its concentration in end-use products is <3.5%. No data was available on skin sensitisation and it cannot be ruled out

The exposure of reformulation workers to the notified polymer at <50% is expected to be minimised by the stated use of enclosed and automated processes and the use of appropriate PPE including eye protection, gloves and coveralls.

If spray application occurs, workers handling the end-use products may have inhalation as well as dermal/ocular exposure to products containing the notified polymer at up to 3.5% concentration. The notifier states that inhalation exposure would be minimised during most coating processes as they will be carried out in spray booths, and respiratory protection would be used if required. Other controls include safe work practices and PPE (gloves, safety goggles and coveralls). No specific controls were described for spray application of leather coatings, however inhalation exposure may be lessened by use of a water curtain.

Provided that adequate control measures are in place to minimise worker exposure, the risk to workers from the use of the notified polymer is not considered to be unreasonable.

#### 6.3.2. Public Health

The notified polymer will only be for industrial use. The general public may come into contact with surfaces that have been coated with coatings containing the notified polymer; however, once cured, the notified polymer is not expected to be bioavailable. Therefore, the risk to public health from exposure to the notified polymer is not considered to be unreasonable.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

## 7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

No manufacturing of the notified polymer will take place in Australia. The notified polymer will be blended for use in architectural coatings, industrial coatings, protective coating systems, automotive OEM coatings and leather finishes. The notified polymer may also be used in sealants, adhesives and fillers. The blending process for the different end uses is expected to be the same.

During the formulation process, an estimated 1% (200 kg) of the total importation volume of the notified polymer is expected to be lost due to spills. The spills are expected to be contained and collected for disposal to landfill. Up to 1% (200 kg) of the total import volume of the notified polymer is anticipated to remain in storage containers as residues. The residue in the storage containers will be cured prior to disposal to landfill. Manufacturing equipment will be rinsed with solvents. It is estimated that less than 1% of the total import volume of the notified polymer will be released to interceptor pits from cleaning of the equipment. The notified

polymer is expected to be flocculated in the interceptor pits and to be removed before the treated effluent is released to the sewage treatment plants. The sludge containing the notified polymer is expected to be disposed of to landfill.

#### RELEASE OF CHEMICAL FROM USE

When coating formulations containing the notified polymer are applied by spray techniques, it is anticipated that between 20-30% of the coating products will form overspray and be collected as waste material. As the application of coating is expected to be conducted at industrial sites in designated spray booths, the overspray is expected to be captured in the spray booth filters or other capture systems. The captured notified polymer is expected to be disposed of to landfill. Application by brush and roller is expected to be efficient, with very little release expected from these application methods.

#### RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to be disposed of to landfill along with the used article at the end of its useful life. The notified polymer is expected to remain associated with the substrate to which it has been applied.

#### 7.1.2. Environmental Fate

No environmental fate data were submitted. The captured overspray and the majority of articles to which the notified polymer will be applied will be disposed of to landfill. The majority of the notified polymer is expected to be cured within an inert polymer matrix adhering to articles following its use in coating applications. In its cured form it is not expected to be mobile, bioavailable or biodegradable. Ultimately, the notified polymer is expected to eventually degrade via biotic and abiotic processes in landfill, or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon, phosphorous and nitrogen.

A small fraction of the notified polymer may be released to the sewerage system due to the cleaning of the reformulation and application equipment. In wastewater treatment processes in sewage treatment plants (STPs), most of the notified polymer is expected to partition to sludge due to its high molecular weight and cationicity. The sludge from the STPs is expected to be removed for disposal to landfill or used on land for soil remediation. The notified polymer is not expected to bioaccumulate based on its high molecular weight.

## 7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified polymer to the aquatic environment will be very limited based on its reported use pattern.

#### 7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The notified polymer contains cationic groups and therefore may be toxic to algae. However, the notified polymer is expected to have very limited exposure to aquatic environment due to its use pattern.

#### 7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has been not calculated for the notified polymer as no ecotoxicity data were submitted. The release of the notified polymer to the aquatic environment will be very limited based on its reported use pattern.

## 7.3. Environmental Risk Assessment

A risk quotient (PEC/PNEC) for the notified polymer was not calculated, as neither a PEC nor PNEC was derived. Release of the notified polymer to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern. The notified polymer is not expected to be bioaccumulative and is expected to slowly degrade in the environment. Based on the assessed use pattern of the notified polymer, it is not expected to pose an unreasonable risk to the environment.

## APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

## **B.1.** Acute toxicity – oral

TEST SUBSTANCE Notified Polymer at 60%

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain Rat/SPF-Wistar (Winkelmann, Paderborn)

Vehicle Water

Remarks - Method The test substance was dosed to the animals by gavage through a

nonflexible tube.

#### RESULTS

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw	
1	3M	1000	0
2	3M	2000	0
3	3F	1000	0
4	3F	2000	0

LD50 >2000 mg/kg bw

Signs of Toxicity The group dosed at 2000 mg/kg bw showed reduced activity during the

first 4 hours after administration.

Effects in Organs A slight hyperaemia in the mucosae of the duodenum was observed in the

2000 mg/kg bw dose group. Weight gains were also reduced in the higher dose group. No other clear pathological findings or macroscopical changes

were observed.

Remarks - Results No mortality at any dose was observed.

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

TEST FACILITY Pharmatox (2001a)

## **B.2.** Irritation – skin

TEST SUBSTANCE Notified Polymer at 60%

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain Rabbit/New Zealand White

Number of Animals 3

Vehicle None (substance in solution - viscous compound-)

Observation Period 1, 24, 48 and 72 h

Type of Dressing Occlusive.

Remarks - Method No significant protocol deviations. The test material was wiped from the

skin after the contact period.

#### **RESULTS**

Lesion	Mean Score* Animal No.		Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period	
	1	2	3			
Erythema/Eschar	1	0.67	1.0	2	< 72 h	0
Oedema	0	0	0	0	=	0

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

Remarks - Results Erythema was observed in 2 animals, but had resolved by the 72 h

observation. No oedema was observed. Weight gain was normal, and no

adverse clinical signs were observed.

CONCLUSION The test substance was slightly irritating to the skin.

TEST FACILITY Pharmatox (2001b)

**B.3.** Irritation – eye

TEST SUBSTANCE Notified Polymer at 60%

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain Rabbit/New Zealand White

Number of Animals 3 Observation Period 72 h

Remarks - Method Observations were made at 1, 2, 4, 8, 24, 48 and 72 h. No significant

protocol deviations.

#### RESULTS

Lesion	Mean Score* Animal No.		Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period	
	1	2	3	ranc	oj my Ejjeci	oj coscivation i criou
Conjunctiva: redness	0	0	0	2	< 24 h	0
Conjunctiva: chemosis	0	0	0	2	< 24 h	0
Conjunctiva: discharge	0	0	0	1	< 24 h	0
Corneal opacity	0	0	0	0	<del>-</del>	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results Reddening, some chemosis and increased secretion were noted after the

application of the test substance but were resolved by the 24 h observation.

CONCLUSION The test substance ws slightly irritating to the eye.

TEST FACILITY Pharmatox (2001c)

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