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July 2014

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

PUBLIC REPORT

Diamide Epoxy Curing Agent

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
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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/1646	3M Australia Pty Ltd	Diamide Epoxy Curing Agent	Yes	≤ 1 tonne per annum	Component of adhesives

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

<i>Hazard classification</i>	<i>Hazard statement</i>
Skin Corrosion/Irritation (Category 2)	H315- Causes skin irritation
Skin Sensitisation (Category 1)	H317- May cause an allergic skin reaction

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R38: Irritating to skin

R43: May cause sensitisation by skin contact

Human health risk assessment

Provided that the recommended controls are being adhered to, under the conditions of the occupational setting described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
 - H315- Causes skin irritation
 - H317- May cause an allergic skin reaction

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

Health Surveillance

- As the notified chemical is a skin sensitizer, 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**

- 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 chemical in the finished product:
 - Avoid skin and eye contact
- 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 chemical in the finished product:
 - Impervious gloves
 - Safety goggles
 - Protective coveralls

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

- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for 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

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical 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 importation volume exceeds one tonne per annum notified chemical;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from component of adhesives or is likely to change 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 (M)SDS for products containing the notified chemical 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)

3M Australia Pty Ltd (ABN: 90 000 100 096)
Building A, 1 Rivett Road
NORTH RYDE NSW 2113

NOTIFICATION CATEGORY

Limited-small volume: Chemical other than polymer (1 tonne or less per year).

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, spectral data, degree of purity, impurities, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: vapour pressure, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, flammability, and autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Diamide Epoxy Curing Agent

MOLECULAR WEIGHT

> 500 Da

ANALYTICAL DATA

Reference NMR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 85%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Dark brown-green, clear to cloudy liquid

Property	Value	Data Source/Justification
Pour point	-12.5 ± 3 °C	Measured
Boiling Point	> 250 °C at 101.3 kPa	Measured
Density	979.7 kg/m ³ at 23 °C	Measured
Vapour Pressure	1.72 x 10 ⁻²⁸ kPa at 25 °C	Estimated. EPI Suite v4.0 (Modified Grain method)
Water Solubility	3.6 × 10 ⁻⁴ g/L Forms emulsion	Measured. The notified chemical is dispersible based on an emulsion formation at concentration greater than 100 mg/L.
Hydrolysis as a Function of pH	Not Determined	The notified chemical contains functional groups that are expected to hydrolyse slowly in the environmental

Partition Coefficient (n-octanol/water)	Not Determined	pH range (4-9) at ambient temperature. Expected to partition to phase boundaries based on its surfactant properties.
Adsorption/Desorption	$\log K_{oc} = 7.8$ at 25 °C	Estimated (KOCWIN v2.00, US EPA 2011). Expected to partition to surfaces from water in the environment based on its surface activity.
Dissociation Constant	Not determined	The notified chemical contains dissociable functionalities. However, it is not expected to be significantly ionised in the environmental pH range of 4–9.
Flash Point	> 93 °C at 101.3 kPa	Closed cup
Flammability	Not expected to be flammable	Based on measured flash point
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions
Explosive Properties	Not expected to be explosive	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not expected to be oxidising	Contains no functional groups that would imply oxidising properties

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemical 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 chemical is not recommended for hazard classification according to the *Globally Harmonised System for the 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 chemical will be imported as a component of highly viscous adhesive products at $\leq 90\%$ concentration.

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

Year	1	2	3	4	5
Tonnes	≤ 1	≤ 1	≤ 1	≤ 1	≤ 1

PORT OF ENTRY

Sydney

IDENTITY OF RECIPIENTS

3M (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING

The finished adhesive products containing the notified chemical will be imported by sea in 50 mL or 200 mL Duo-Syringe cartridges designed for use in 3M applicators. When used as a void filling compound the finished product containing the notified chemical will be packed in 950 mL foil sachets or 500 mL stainless steel cans. The products will be distributed within Australia by road.

USE

The notified chemical will be used as a curing agent in two-part epoxy amide adhesives for bonding applications in automotive, aerospace and industrial markets. The notified chemical will be present in the Part A component at a concentration of 40-90%. After mixing with Part B, the concentration of the notified chemical in the resulting adhesive ranges from 12 to 45%. The adhesive can be used to bond various types of substrates such as plastics, metals, rubber, or glass.

OPERATION DESCRIPTION

The products containing the notified chemical will be supplied in either purpose-built dual chamber cartridges, 500 mL stainless steel cans or 950 mL foil sachets.

The cartridges will be used with either a manual or pressure-assisted applicator to depress the plunger and slowly extrude the adhesive onto the surface. The operator will cut the end of the cartridge and fit the cartridge into the applicator. The adhesive will be extruded through a mixing nozzle, which mixes Part A containing the notified chemical at $\leq 90\%$ concentration and Part B in a fixed ratio. The adhesive has a curing time of 10 minutes (work life) and 2 hours for complete bonding. The bond line can be heated using a heat gun to 60-80 °C to accelerate the curing. Any excess adhesive will be removed using a spatula or cloth.

When the product is supplied in the cans or sachets, these containers will be opened and the contents manually squeezed out or removed with a spatula or trowel and placed in a separate container for mixing with Part B prior to application to the treated surface.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	2	12-24
End-use	8	200

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the notified chemical as a component of the adhesive finished products at up to 90% concentration only in the event of accidental rupture of containers.

End-use

Workers may be exposed to the notified chemical at concentrations up to 90% when manually mixing the two components of the adhesive, during application (particularly when not using a cartridge) and when removing excess adhesive. The most likely route of exposure during these operations will be dermal. Ocular and oral exposure routes are also possible. Inhalation exposure to the notified chemical is unlikely due to its relatively high molecular weight, low vapour pressure and high viscosity of the product in which it is contained. The potential for exposure should be reduced by the expected use of PPE by these workers.

Once the adhesive has cured and dried, the notified chemical will become part of a polymeric matrix and will not be available for exposure.

6.1.2. Public Exposure

The finished product will be used by industry professionals only. The public may come into contact with surfaces treated with the adhesives. However, once the adhesives are cured and dried, the notified chemical will become part of a polymeric matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

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

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rabbit, skin irritation	severely irritating
Guinea pig, skin sensitisation –Maximisation test.	evidence of sensitisation

Irritation and sensitisation.

Two studies were performed to assess skin irritation/corrosion under semi-occluded conditions. In the first study, the skin of a single rabbit exhibited corrosive effects including subcutaneous haemorrhage and possible necrosis. No signs of irritation were observed at 21 days; however, scar tissue remained. In the second study conducted with three test animals and three exposure times (3 minutes, 1 hour and 4 hour), no evidence of corrosion was observed at any of the test sites for any of the exposure periods. Slight dermal irritation was observed as a result of 3-minute exposure; slight to moderate irritation was observed as a result of the 1-hour exposure; and moderate to severe irritation was observed as a result of the 4-hour exposure. Based on the weight of evidence the notified chemical is considered not to be corrosive but is considered to be severely irritating to the skin. Due to the results of these studies, the notified chemical is expected to be severely irritating to the eyes.

In a Guinea Pig Maximisation Test, the notified chemical was found to be an extreme dermal sensitiser. In the sensitisation study, cases of mild to intense dermal reactions to the challenge application were observed in 19/20 test animals. Desquamation was observed at the challenge sites in 7/20 test animals. Nineteen out of 20 animals in the test group (95%) are considered to have been sensitised to the notified chemical.

Health hazard classification

Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

<i>Hazard classification</i>	<i>Hazard statement</i>
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Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R38: Irritating to skin

R43: May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified chemical causes skin irritation and sensitisation. Dermal exposure to the notified chemical at up to 90% concentration may occur when manually mixing components and cleaning up excess material as well as during any potential spills. This risk of exposure is expected to be reduced given use of PPE such as impervious gloves and goggles. Once the adhesive has cured and dried, the notified chemical will become part of a polymeric matrix and will not be available for exposure.

Under the proposed usage conditions and provided that appropriate PPE is used to minimise exposure, the risk of exposure to the notified chemical to workers is not considered to be unreasonable.

6.3.2. Public Health

The public will not be exposed to the notified chemical except in the unlikely event of an accident or spill, hence, the risk to the public is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia and therefore, no release of the notified chemical to the environment is expected from this activity. The imported cartridges containing the notified chemical are designed to minimise the release of the notified chemical to the environment during importation, storage and transport. If release does occur as a result of an accident, it is expected to be contained, collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

A small amount of the notified chemical may be released to the environment as a result of spills during the application of the adhesive products. Any spilt notified chemical is expected to be collected and be disposed of to landfill. Excess adhesive may be cleared with a cloth or spatula. Adhesive on cleaning clothes and spatulas (up to 2% of the total import volume) is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical will be cured into an inert polymer matrix expected to be associated with articles after application. It is expected to share the fate of the articles to which it is applied and is disposed of to landfill or be subjected to metal recycling processes. Residual notified chemical in empty cartridges (2%) is expected to be disposed of to landfill along with empty cartridges in accordance with local regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified chemical is expected to be cured into an inert polymer matrix during use and therefore not expected to be mobile, bioavailable or readily biodegradable in this form. Bioaccumulation of the uncured notified chemical is unlikely due to its potential surface activity and limited potential for aquatic exposure. The notified chemical is expected to degrade in landfill or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified chemical 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 were submitted. Chemicals with potential cationic functionality may have excess toxicity towards aquatic life. However, the notified chemical is not expected to be bioavailable based on its use and being cross-linked into a cured and inert polymer matrix.

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) has not been calculated for the notified chemical 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 ($Q = \text{PEC}/\text{PNEC}$) for the notified chemical has not been calculated as significant quantities are not expected to be released to the aquatic environment. The majority of the notified chemical will eventually be disposed of to landfill associated with the articles to which it has been applied. In its cured state the notified chemical will be bound into an inert matrix and is not likely to leach from the inert matrix. On the basis of the assessed use pattern the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Pour point** -12.5 ± 3 °C

Method ASTM D97.

Remarks In a preliminary freezing/melting point study, the substance was observed to become more viscous without crystallisation as it is cooled; therefore the pour point was determined.

Test Facility 3M Analytical (2012)

Boiling Point > 250 °C at 101.3 kPa

Method ASTM D1120-94 Standard Test Method for Boiling Point of Engine Coolants.

Remarks Test substance did not boil up to 250 °C.

Test Facility 3M Analytical (2012)

Density 979.7 kg/m³ at 23°C

Method OECD TG 109 Density of Liquids and Solids.

Remarks Pycnometer method

Test Facility 3M Analytical (2012)

Water Solubility 0.36 mg/L at 20 °C

Method OECD TG 105 Water Solubility (Flask Method)

Remarks The water solubility was evaluated by two different modified shake flask procedures. The first was conducted by placing accurately weighed notified chemical in a vial, submerging into 5 L of water and stirring overnight at 22.4°C. The amount of the notified chemical lost from the vial was determined gravimetrically.

In the second procedure accurately weighed notified chemical was placed into 40 mL of water in a sealed centrifuge tube. The tube was mixed overnight on a rotisserie shaker at 22.4°C. The non-solubilised fraction of the notified chemical was determined gravimetrically.

Results from first screening indicated the solubility of the notified chemical as tested was 0.36 mg/L. The report also concluded that as the notified chemical is a mixture of monomers, dimers and higher weight oligomers, the overall solubility will change slightly, depending on the exact distribution in that particular batch. The second study confirmed only that the solubility was < 100 mg/L. While the solubility may vary, the results also showed that the notified chemical is dispersible into a semi-stable emulsion in pure water at concentrations above 100 mg/L.

Test Facility 3M Environmental (2013)

Flash Point > 93 °C at 101.3 kPa

Method ASTM D-3278-96 e-1 Flash points of Liquids by Small Scale Closed-Cup Apparatus

Remarks The test substance was ramped between 70 °F to 200 °F at a rate of 5 °F/minute and tested every two degrees with no flash point detected.

Test Facility 3M Analytical (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Irritation – skin**

TEST SUBSTANCE	Notified chemical (purity not provided)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	1
Vehicle	Test substance administered as supplied
Observation Period	21 days
Type of Dressing	Semi-occlusive.
Remarks - Method	Observations were made at 30 minutes, 24, 48, 72 and 96 hours and at 7, 14 and 21 days after patch removal. The animal was exposed to the test material for 4 hours

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1			
<i>Erythema/Eschar</i>	4	4	> 14 days	0
<i>Oedema</i>	3	3	> 14 days	0

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

Remarks - Results Severe erythema and moderate oedema was observed that persisted to Day 7 and cleared by Day 21. Subcutaneous haemorrhage (observed at 30 minutes post-exposure), possible necrotic area (observed between 24 hours and 7 days) and scar tissue (observed between Day 14 and Day 21) was also observed. All irritation, with the exception of the scar tissue, cleared in the animal by the Day 21 observation.

CONCLUSION The notified chemical is corrosive to the skin.

TEST FACILITY Hazleton (1995a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified chemical (purity not provided)
METHOD	UN/DOT Regulations similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test substance administered as supplied
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	Observations were made at 30 minutes, 24, 48, 72 and 96 hours and at Day 7 after patch removal. Animals were exposed to the test material for 3 minutes, 1 hour, and 4 hours.

RESULTS**3-minute exposure period**

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	1	1	1	1	> 7 days	1

<i>Oedema</i>	0	0	1	1	< 7 days	0
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1-hour exposure period

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	1	2	1	2	> 7 days	1
<i>Oedema</i>	0	2.3	1.3	3	> 7 days	1

4-hour exposure period

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	2	3	3	3	> 7 days	2
<i>Oedema</i>	1.7	2	2.7	3	> 7 days	2

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

Remarks - Results

No evidence of corrosion was observed at any of the test sites for any animals. Slight dermal irritation was observed as a result of 3-minute exposures, slight to moderate irritation was observed after the 1-hour exposures and moderate to severe irritation was observed as a result of the 4-hour exposures. In the cases of the 3minute 1-hour and 4-hour exposure all the signs of irritation had not subsided at the end of the observation period.

CONCLUSION

The notified chemical is severely irritating to the skin.

TEST FACILITY

Hazelton (1995b)

B.3. Skin sensitisation

TEST SUBSTANCE

Notified chemical (purity not provided)

METHOD

Species/Strain

PRELIMINARY STUDY

Similar to OECD TG 406 Skin Sensitisation – Maximization test
EC Directive 96/54/EC B.6 Skin Sensitisation - Maximization test
Guinea pig/Crl:(HA)BR
Maximum Non-irritating Concentration:
intradermal: none found
topical: 50%

MAIN STUDY

Number of Animals
INDUCTION PHASE

Test Group: 20 Control Group: 10
Induction Concentration:
intradermal: 1%
topical: 100%

Signs of Irritation

Mild to moderate erythema and oedema reactions with scab formation were observed during the induction phase in the control and test group.

CHALLENGE PHASE

1st challenge

Remarks - Method

topical: 50%
The control animals were pre-treated with 10% sodium lauryl sulfate prior to topical induction. Mineral oil was used as the diluent to prepare the test concentrations.

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after: 1st challenge</i>
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		<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	50%	18/20	19/20
<i>Control Group</i>	0%	0/10	0/10

Remarks - Results

Nineteen of the 20 animals in the test group exhibited mild to intense dermal reactions challenged with the test substance at 50% concentration in mineral oil. Desquamation was also observed within the challenge sites of 7 animals in the test group. Eighteen of the 20 animals at the 24-hour point and 19/20 animals at the 48-hour point exhibited a response.

CONCLUSION

The notified chemical is a skin sensitiser under the conditions of the test.

TEST FACILITY

Covance (2000)

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