

May 2014

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

PUBLIC REPORT

LTD/1711: Dodecanoic acid, 1,1'-[1,6-hexanediylbis[nitrilo(2,2-dimethyl-1-propanyl-3-ylidene)]] ester

LTD/1712: Dodecanoic acid, 3-[[3-[[[2,2-dimethyl-3-[(1-oxododecyl)oxy]propylidene]amino]methyl]-3,5,5-trimethylcyclohexyl]imino]-2,2-dimethylpropyl ester

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 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/1711	Sika Australia Pty Ltd	Dodecanoic acid, 1,1'-[1,6-hexanediylbis[nitrilo(2,2-dimethyl-1-propanyl-3-ylidene)]] ester	Yes	0.99 tonnes per annum	Component of industrial sealants
LTD/1712	Sika Australia Pty Ltd	Dodecanoic acid, 3-[[3-[[[2,2-dimethyl-3-[(1-oxododecyl)oxy]propylidene]amino]methyl]-3,5,5-trimethylcyclohexyl]imino]-2,2-dimethylpropyl ester	Yes	0.99 tonnes per annum	Component of industrial sealants

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified chemicals are 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>
Skin sensitisation (Category 1)	H317 – May cause an allergic reaction

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

R43 May cause sensitisation by skin contact

Human health risk assessment

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

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

Environmental risk assessment

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemicals should be classified as follows:
 - H317 – May cause an allergic reaction
- The following classifications should be considered for use for products/mixtures containing the notified chemicals:
 - Conc. ≥1%: H317

Health Surveillance

- As the notified chemicals have skin sensitisation potential, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin 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 chemicals:
 - Avoid contact with skin
- 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 chemicals:
 - Coveralls and impervious gloves

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 chemicals 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 chemicals should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemicals 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 chemicals 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 chemicals, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemicals are 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 chemicals;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified chemicals has changed from component of industrial sealants, or is likely to change significantly;

- the amount of notified chemicals being introduced has increased, or is likely to increase, significantly;
- the notified chemicals have begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the notified chemicals 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's of products containing the notified chemicals provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

Sika Australia Pty Ltd (ABN: 12 001 342 329)
55 Elizabeth Street
WETHERILL PARK NSW 2164

NOTIFICATION CATEGORY

LTD/1711: Limited-small volume: Chemical other than polymer (1 tonne or less per year).

LTD/1712: Limited-small volume: Chemical other than polymer (1 tonne or less per year) – Group Assessment.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

LTD/1711: Hardener LH (> 90% notified chemical)

LTD/1712: Hardener LI (> 90% notified chemical)

CAS NUMBER

LTD/1711: 613222-52-9

LTD/1712: 932742-30-8

CHEMICAL NAME

LTD/1711: Dodecanoic acid, 1,1'-[1,6-hexanediylbis[nitrilo(2,2-dimethyl-1-propanyl-3-ylidene)]] ester

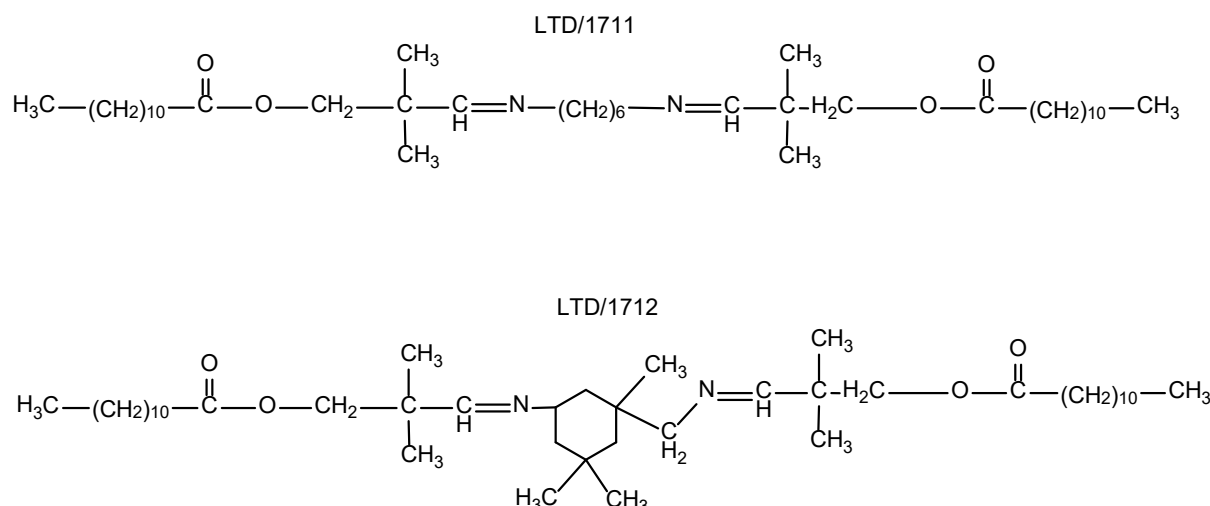
LTD/1712: Dodecanoic acid, 3-[[3-[[[2,2-dimethyl-3-[(1-oxododecyl)oxy]propylidene]amino]methyl]-3,5,5-trimethylcyclohexyl]imino]-2,2-dimethylpropyl ester

MOLECULAR FORMULA

LTD/1711: C₄₀H₇₆N₂O₄

LTD/1712: C₄₄H₈₂N₂O₄

STRUCTURAL FORMULA



MOLECULAR WEIGHT

LTD/1711: 649.1 Da

LTD/1712: 703.2 Da

ANALYTICAL DATA

Reference NMR and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

LTD/1711: 96-100%

LTD/1712: 95-100%

IMPURITIES

LTD/1711

<i>Chemical Name</i>	Dodecanoic acid, 2,2-dimethyl-3-oxopropyl ester
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<i>CAS No.</i>	102985-93-3	<i>Weight %</i>	-
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<i>Chemical Name</i>	1-(2,2-Dimethyl-3-lauroyloxopropylidene)-amino)-6-lauroylamino-hexane
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<i>CAS No.</i>	Not assigned	<i>Weight %</i>	-
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LTD/1712

<i>Chemical Name</i>	Dodecanoic acid, 2,2-dimethyl-3-oxopropyl ester
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<i>CAS No.</i>	102985-93-3	<i>Weight %</i>	-
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ADDITIVES/ADJUVANTS

None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless to light yellow liquid (LTD1711 & LTD/1712)

LTD/1711

Property	Value	Data Source/Justification
Melting Point	233 °C	Calculated (mean or weighted MP)
Boiling Point	612 °C (pressure unknown)	Calculated (adapted Stein & Brown method)
Density	910 kg/m ³ at 20 °C	SDS
Vapour Pressure	2.68 × 10 ⁻¹⁴ kPa at 25 °C	Calculated (modified Grain method)
Water Solubility	<< 1 × 10 ⁻³ g/L at 25 °C	Calculated (WSKOW v1.42; US EPA, 2011)

Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities. However, the notified chemical is not expected to significantly hydrolyse under normal environmental conditions (pH 4 – 9).
Partition Coefficient (n-octanol/water)	log Pow > 8	Calculated (KOWWIN v1.68; US EPA, 2011)
Adsorption/Desorption	log K _{oc} > 5 (MCI method) log K _{oc} > 5 (Kow method)	Calculated (KOCWIN v2.00; US EPA, 2011)
Dissociation Constant	pKa ~ 7	Estimated by analogy. Contains ionisable functionalities. The notified chemical has potential to ionise under normal environmental conditions of pH 4 – 9.
Particle Size	Not determined	Liquid
Flash Point	209 °C (closed cup) (pressure unknown)	SDS
Autoignition Temperature	Not determined	Expected to be high based on the flashpoint.
Explosive Properties	Not determined	Contains no explosives that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties.

LTD/1712

Property	Value	Data Source/Justification
Melting Point/Freezing Point	273 °C	Calculated (mean or weighted MP)
Boiling Point	645 °C (pressure unknown)	Calculated (adapted Stein & Brown method)
Density	900 kg/m ³ at 20 °C	SDS
Vapour Pressure	1.19 × 10 ⁻¹⁵ kPa at 25 °C (or 20 °C)	Calculated (modified Grain method)
Water Solubility	<< 1 × 10 ⁻³ g/L at 25 °C	Calculated (WSKOW v1.42; US EPA, 2011)
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities. However, the notified chemical is not expected to significantly hydrolyse under normal environmental conditions (pH 4 – 9).
Partition Coefficient (n-octanol/water)	log Pow > 8	Calculated (KOCWIN v2.00; US EPA, 2011)
Adsorption/Desorption	log K _{oc} > 5 (MCI method) log K _{oc} > 5 (Kow method)	Calculated (KOCWIN v2.00; US EPA, 2011)
Dissociation Constant	pKa ~ 7	Estimated by analogy. Contains ionisable functionalities. The notified chemical has potential to ionise under normal environmental conditions of pH 4 – 9.
Particle Size	Not determined	Liquid
Flash Point	> 180 °C (closed cup) (pressure unknown)	SDS
Autoignition Temperature	Not determined	Expected to be high based on the flashpoint.
Explosive Properties	Not determined	Contains no explosives that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties.

Reactivity

The notified chemicals are 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 chemicals are 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 chemicals will be imported as a component of finished sealant products at concentrations up to 3%.

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

LTD/1711

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	0.99	0.99	0.99	0.99	0.99

LTD/1712

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	0.99	0.99	0.99	0.99	0.99

PORT OF ENTRY

Sydney

IDENTITY OF RECIPIENTS

Sika Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The sealant products containing the notified chemicals at a concentration of up to 3% will be imported in 300 mL cartridges and are expected to be transported by road to end users.

USE

The notified chemicals will be used as the hardener in one-pack moisture-cured polyurethane sealants (up to 3% concentration) for professional boat building and construction markets. The sealants will be used for original equipment manufacturer (OEM) and aftermarket repairs.

OPERATION DESCRIPTION

The notified chemicals will be imported as a component (up to 3%) of finished polyurethane sealant products and will be used for professional corking of wooden decks on boat/yachts or sealing around port holes, mostly in dry dock or at the marina. The sealants may also be used in general construction applications by professional builders. The sealants will be dispensed directly from the cartridge via a nozzle into cavities which require sealing, using a manual application gun or a compressed air-assisted gun. Any excess sealant will be scrapped off and wiped clean with a cloth.

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 warehousing	2-4	12-14
Marine applicators	8	50-200
Construction applicators	8	100-200

EXPOSURE DETAILS

Exposure of transport and storage workers is not expected except in the event of accidental breach of packaging. As the sealant is applied with a manual application gun or a compressed air-assisted gun, dermal exposure to the notified chemicals is possible during application. Ocular exposure, though less likely, is also possible from splatter during application. Inhalation exposure would be limited by the low vapour pressures ($< 5 \times 10^{-14}$ kPa) of the notified chemicals.

Exposure to the notified chemicals will be minimised by the use of impermeable gloves and protective coveralls. Typically, the application of sealant is carried out in well ventilated areas. However, a half-face respirator will be used when ventilation is poor or when work is carried out in confined spaces. Once the sealant has cured, the notified chemicals become bound within a matrix and hence, are unavailable for exposure.

6.1.2. Public Exposure

The sealant products containing the notified chemicals will only be available to industrial end users and will not be sold to the general public. The potential for general public exposure to the notified chemicals during transportation of the imported product containing the notified chemicals is likely to be negligible and would only occur in the event of an accident.

After curing, the notified chemicals are expected to be irreversibly bound to the substrate and will not be available for exposure.

6.2. Human Health Effects Assessment

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

<i>Endpoint</i>	<i>Test Substance</i>	<i>Result and Assessment Conclusion</i>
Guinea pig, skin sensitisation – adjuvant test.	LTD/1711: Hardener LH	evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay	LTD/1712: Hardener LI	evidence of sensitisation

Toxicokinetics, metabolism and distribution

Based on the relatively high molecular weight (> 600 Da) of the notified chemicals, the potential of the notified chemicals to cross the gastrointestinal (GI) tract or to be dermally absorbed after exposure is expected to be limited.

Sensitisation

A Guinea Pig Maximisation Test (Magnusson and Kligman) on Hardener LH (LTD/1711) carried out according to OECD test guideline 406 gave a positive result, indicative of skin sensitisation potential for the chemical.

Hardener LI (LTD/1712) was positive in a mouse Local Lymph Node Assay (LLNA) carried out according to OECD test guideline 429.

Health hazard classification

Based on the available information, the notified chemicals are 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>
Skin sensitisation (Category 1)	H317 – May cause an allergic reaction

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

R43 May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified chemicals are classified as skin sensitisers.

Professional applicators apply the sealant products containing the notified chemicals at concentrations up to 3%. At these concentrations there is the potential risk of sensitisation from dermal exposure. This risk should be minimised by the stated use by the notifier of PPE, including impermeable gloves and protective coveralls.

Therefore, under the occupational settings described, the risk to the health of workers from use of the notified chemicals is not considered to be unreasonable.

6.3.2. Public Health

The public is not expected to be exposed to the notified chemicals; hence, the risk to public health 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 chemicals are not manufactured or reformulated in Australia; therefore there will be no release to the environment from these activities.

RELEASE OF CHEMICAL FROM USE

The sealants containing the notified chemicals will be used mainly for sealing of decking and around port holes for professional boat building and construction markets. The application is expected to take place in dry docks and above the water line. Therefore, release of the notified chemicals to the aquatic system is not expected. Spills and leaks (0.5% of the total import volume) of the sealants containing the notified chemicals are expected to be contained and disposed of to landfill. Release of the notified chemicals to the environment is expected to occur only in the cured state. Waste of excess sealant from application (1 to 5% of the total import volume) and residues in empty containers (1 to 5% of the total import volume) are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Notified chemicals in cured sealant are expected to share the fate of the substrate to which it has been applied and are predominantly expected to be disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted. After curing, the notified chemicals will be cross-linked in the sealant matrix. Notified chemicals in cured sealant wastes that are disposed of to landfill are expected to remain associated with the substrate to which it has been applied. In their cured form, the notified chemicals are not expected to be bioavailable nor biodegradable. Notified chemicals in solid waste disposed of to landfill are not likely to be mobile due to their expected limited water solubility and incorporation into the cross-linked sealant matrix. The notified chemicals are not expected to be bioaccumulative in the form of cured sealant matrix. The notified chemicals are expected to eventually degrade in landfill to form water, and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) was not calculated as, based on their reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The notified chemicals in the cured sealant matrix are not expected to be bioavailable nor bioaccumulative.

7.2.1. Predicted No-Effect Concentration

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

7.3. Environmental Risk Assessment

The risk quotients ($Q = PEC/PNEC$) for the notified chemicals have not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on their reported use pattern. The majority of the notified chemicals will eventually be disposed of to landfill following their use in sealant. The cured notified chemicals in sealant matrix are unlikely to leach or be bioavailable. On the basis of the assessed use pattern, the notified chemicals are not considered to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Skin sensitisation

TEST SUBSTANCE	Hardener LH (LTD/1711)	
METHOD	OECD TG 406 Skin Sensitisation - Magnusson and Kligman. EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman.	
Species/Strain	Guinea pig/Dunkin Hartley LAL/HA/BR	
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 0.1% (w/v) topical: 100% (w/v)	
MAIN STUDY		
Number of Animals	Test Group: 10	Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 5% topical: 100%	
Signs of Irritation	Not reported	
CHALLENGE PHASE		
challenge	topical: 100%	
Remarks - Method	Minor protocol deviations occurring during the study were not considered to have compromised the validity or integrity of the study.	
	All animals were treated with 10% sodium dodecyl sulphate 24 hours prior to topical induction application.	

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after: challenge</i>	
		<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	100%	4/10	4/10
<i>Control Group</i>	100%	0/5	0/5

Remarks - Results	The dermal scores observed on the skin surface of previously sensitised guinea pigs represented intense, confluent erythema and swelling (scores 2-3).
	The body weight changes were normal.

CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
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TEST FACILITY	LAB International Research Hungary Ltd (2005)
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A.2. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Hardener LI (LTD/1712)
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain	Mouse/CBA/Ca Ola Hsd
Vehicle	Acetone/olive oil (4:1) (AOO)
Remarks - Method	No protocol deviations

RESULTS

<i>Concentration (% w/w)</i>	<i>Proliferative response (DPM/lymph node)</i>	<i>Stimulation Index (Test/Control Ratio)</i>
<i>Test Substance</i>		
0 (vehicle control)	234.5	1.0
25	954.9	4.1
50	1127.9	4.8
100	1454.8	6.2
<i>Positive Control (α-Hexylcinnamaldehyde)</i>		
0 (AOO)	232.2	1.0
25	2625.2	11.3
0 (DMF)	199.1	1.0
25	1406.1	7.1
0 (DMSO)	424.3	1.0
25	2332.1	5.5

Remarks - Results

As the SI value at the lowest dose level was above the threshold of 3, the EC3 from the study (theoretical concentration causing SI of 3) could not be estimated by the study authors.

No animals showed any abnormalities with regard to general condition or body weight change.

CONCLUSION

There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY

LAB Research Ltd (2008)

BIBLIOGRAPHY

- LAB International Research Centre Hungary Ltd (2005) [Hardener LH]: Test for Sensitisation (Guinea Pig Maximisation Test) (LAB Study Code: 04/915-104T, June, 2005). LAB International Research Centre Hungary Ltd, Szabadsagpuszta, Hungary (Unpublished report provided by the notifier).
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