File No: STD/1337

December 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Sovermol 1102

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cognis Australia Pty Ltd (ABN 87 006 374 456)
4 Saligna Drive
Tullamarine VIC 3043

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Spectral Data, Formulation Consitutents, Identity of Impurities, Import Volumes and Identitiy of Recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for the use of analogue data for acute oral and dermal toxicity, acute skin & eye irritation, repeat dose (28-days) oral toxicity, and in vivo micronucleus studies.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sovermol 1102

MOLECULAR WEIGHT
The notified polymer is a reaction mixture with two major reaction components, major component 1 (MW <500) and major component 2 (MW <1000).

ANALYTICAL DATA
Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Yellow viscous liquid.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Between -19°C and 5°C	Measured
Boiling Point	>298°C at 101.3 kPa	Measured
Density	969 kg/m^3 at 20°C	Measured
Vapour Pressure	≤0.006 kPa at 20°C	Measured
Water Solubility	0.22 g/L at 20°C	Measured
Partition Coefficient (n-octanol/water)	log Pow >5.7 at 20°C	Measured
Particle Size	Not applicable	Notified polymer is a liquid
Flash Point	212°C at 101 kPa	MSDS
Flammability limits	Not determined.	--
Autoignition Temperature	Not determined	--
Explosive Properties	Not expected to be explosive	Estimated on basis of structure

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

Hydrolysis (Abiotic degradation)
The notified polymer contains hydrolysable functionality, but this is not expected to occur within the environmental pH range of 4-9.

Adsorption/Desorption
Based on the structure measured water solubility, the notified polymer is expected to readily adsorb to soil and sediment.

Reactivity
The notified polymer is expected to be stable under all normal storage and handling conditions. It is not highly reactive but is designed for specific further reaction via hydroxy groups with isocyanate groups of the second part of a polyurethane system, to create a solid article or film.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia and will be imported into Australia as Sovermol 1102 containing >99% of the notified polymer. In future it may also be imported as a formulated product containing 10-30% of the notified polymer.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	3-10	10-30	10-30	30-100	30-100

PORT OF ENTRY
Melbourne, Brisbane or Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Cognis Australia Pty Ltd
4 Saligna Drive
Tullamarine VIC 3043

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 200 kg drums or 1000 kg intermediate bulk containers (IBC). The imported polymer will be stored at a warehouse in Melbourne, prior to distribution to one customer by road.

USE
The notified polymer is a polyol used in the manufacturing of polyurethanes adhesives for construction and civil engineering projects.

OPERATION DESCRIPTION
The notified polymer will be imported into Australia in a product (Sovermol 1102) or as a formulated product containing 10-30% notified polymer. Following importation, the notified polymer will be stored at a warehouse prior to distribution to one customer in Melbourne. If imported as a concentrated product containing >99% notified polymer, the notified polymer will be blended with other components to form products (containing 10-30% notified polymer) that will be used as an adhesive in hydraulic or civil engineering.

During formulation the transfer of the notified polymer to the blender is a closed and automated system and the blending vessel is also closed, except for sampling. The packaging system is also a closed system (by drum-filling machine) but machine dispensing head is taken from drum to drum manually. A local exhaust ventilation system serves the open bung during packaging.

Blending and packing equipment is occasionally cleaned between campaigns of different products. Clean out (if required) is carried out by wash out with base material which is preserved for use in next campaign. Blender is optimally drained under low air pressure so limited residue in blender may not require wash out.

At the end user sites, the product containing the notified polymer is typically processed by mixing first with the other components of the polyurethane adhesive. The adhesive is then combined with construction materials and is cured to become an article or structure. As the notified polymer will be mixed with other ingredients in different ratios, the exact concentration of the notified polymer in final end-use mixtures is not available. The end-use mixture containing the notified polymer is applied by trowelling, tumble mixing, spraying, dripping or any other similar method.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Storage and transport	2	75 mins/week	48 weeks/year
Warehouse	3	90 mins/week	48 weeks/year
Store person	1	6-8 hours/week	48 weeks/year
Process operator	1	40 hours/week	48 weeks/year
End user	20	20 hours/week	48 weeks/year
Packaging recyclers	1	1 hour/week	48 weeks/year
Construction workers	>100	10 hours/week	20 weeks/year

Exposure Details

Transport and storage

Transport and storage workers are not likely to be exposed to the notified polymer except in the case of an accident involving damage to the packaging.

Adhesive Formulation

Inhalation exposure is not expected as the notified polymer is a liquid with a low vapour pressure. Dermal and accidental ocular exposure may occur during formulation processes such as decanting of the notified polymer into the blender, sampling and testing for quality assurance, packaging, cleaning and maintenance.

Due to the enclosed/semi-enclosed nature of the blending process, decanting and packaging, the greatest potential for exposure is expected to occur during sampling and testing for quality assurance, cleaning and

maintenance. Exposure is expected to be minimised by the use of engineering controls, such as local exhaust ventilation, as well as the use of personal protective equipment (PPE) such as chemical resistant gloves, impervious protective clothing, splash goggles or safety glasses with side-shields. It is also expected that organic cartridge respirators will also be worn if vapour or misting occurs.

End use
The final concentration of the notified polymer in end-use mixture is not known, as the formulated product (containing 10-30% notified polymer) will be mixed with the component of the polyurethane adhesive and then combined with construction materials in different ratios. The scale of use of the final mixture will vary, as will the method of application, and in some cases there would be manual handling of the mixtures. The end-use will be carried out on varied construction and civil engineering sites, in multiple steps, with the potential for spillage during use or for residues to be left on equipment. However the potential for exposure would be reduced by the low concentration of the notified polymer in the product (maximum 30%) and by controls in place for handling the isocyanate component of the polyurethane. Once mixed with the other polyurethane component and cured into the final article, the notified polymer would not be bioavailable.

Any potential for exposure will be further managed by ensuring that all end use operators wear the appropriate personal protective equipment (PPE). Recommended PPE for end use of the polyurethane adhesive includes hand and eye protection, and respiratory protection if ventilation is inadequate.

6.1.2. Public exposure
The notified polymer and the formulated products containing the notified polymer are not intended to be used by the public. Therefore, public exposure to the notified polymer during formulation and use of the formulated adhesives will not occur. The public may have contact with articles or structures containing the notified polymer, however it will be chemically reacted within the polyurethane adhesive, and will not be bioavailable.

The potential for exposure of the general public to the notified polymer during normal industrial storage, handling and transportation is also expected to be negligible, except in the case of an accident where the packaging is breached.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer and structurally related analogues are summarised in the table below. The details of the toxicological investigations can be found in Appendix B.

Endpoint	*Test Substance*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Analogue 1	oral LD50 >2000 mg/kg bw low toxicity
Rat, acute dermal toxicity	Analogue 2	LD50 > 2000 mg/kg bw low toxicity
Rat, acute inhalation toxicity	-	not determined
Rabbit, skin irritation	Analogue 1	non-irritating
Rabbit, eye irritation	Analogue 1	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	Notified polymer	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	Analogue 2	NOAEL = 100 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	Notified polymer	non mutagenic
Genotoxicity – in vivo mouse micronucleus test	Analogue 2	non genotoxic

Toxicokinetics, metabolism and distribution.
No data was available to assess toxicokinetics, metabolism and distribution of the notified polymer. As the major components of the reaction mixture have molecular weights of less than 1000, dermal absorption is possible. However, based on high partition coefficients (log Pow >5.7) and the lack of systemic effects in the acute dermal toxicity study, dermal absorption of the notified polymer is expected to be limited.

Acute toxicity.
Analogue data indicated that the notified polymer is likely to be of low acute oral and dermal toxicity in rats. Toxicity via inhalation has not been tested.

Irritation and Sensitisation.
Analogue 1 chemical was not irritating to the skin of rabbits. However, analogue 1 chemical was slightly irritating to the eyes of rabbits. There was no evidence of skin sensitisation of the notified polymer in local lymph node assay.

Repeated Dose Toxicity
In a 28 day subacute oral toxicity study in rats on analogue chemical 2, increased liver weight (slight in females, significant in males), degenerative changes in the kidneys, increases in alanine aminotransferase levels, slightly decreased haematocrit and clearly decreased erythrocyte values (males only) were observed at 1000 mg/kg bw/day. Minor variations of the same haematological values were also observed in animals treated at a dosage level of 500 mg/kg bw/day, but not at a dosage level of 100 mg/kg bw/day. The NOAEL in male and female rats of 100 mg/kg bw is therefore based on the variations seen in the haematological values at 500 mg/kg bw.

Mutagenicity.
The notified polymer was found to be negative in a bacterial reverse mutation test. Analogue 2 chemical showed no evidence of clastogenicity in a mouse micronucleus test. Therefore, based on the available information, the notified polymer is unlikely to be genotoxic.

Health hazard classification
Based on the available data, the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Analogue data indicated that the notified polymer is likely to be of low acute oral and dermal toxicity in rats. The data also indicated that the notified polymer is unlikely to be a skin irritant, however, slight eye irritation potential of the notified polymer cannot be ruled out. There was no evidence of skin sensitisation of notified polymer in local lymph node assay. The notified polymer is unlikely to be genotoxic.

In a 28 day subacute oral toxicity study in rats on an analogue chemical, the NOAEL was 100 mg/kg bw, based on liver and kidney effects seen at 1000 mg/kg bw, and the variations seen in the haematological values at 500 mg/kg bw. Therefore, the primary risk to workers from repeated exposure to the notified polymer is the possibility of slight eye irritation and development of systemic toxicity effects.

There is a potential for exposure to the notified polymer during various processes involving the notified polymer such as transport, storage, adhesive formulation (decanting of the notified polymer into the blender, sampling and testing for quality assurance, R&D, packaging, cleaning and maintenance), and end-use application (including cleaning, and maintenance). Once incorporated in the polyurethane adhesive and the final articles or structures, the notified polymer will not be bioavailable. Considering the use of PPE, engineering controls and the likelihood of limited dermal absorption, the level of risks to workers presented by the use of notified polymer is expected to be low and is not considered to be unacceptable.

6.3.2. Public health
As the notified polymer and the formulated products containing the notified polymer are not intended to be used by the public, exposure to the general public from the use of the notified polymer during formulation and in formulated sales products is not expected. Although the public may have contact with articles or structures containing the notified polymer, it will be incorporated in the matrix and will not be bioavailable. Therefore, based on low hazard and very low exposure, the risk to general public from the use of 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

Release from reformulation is expected to be limited to residual in import containers and arising from cleaning of blending equipment. Used import containers are expected to be sent to reconditioners for cleaning and reuse. Residual notified polymer is expected to account for <1.6% of the annual import volume, and will be extracted using solvents. Extracted notified polymer is expected to be thermally decomposed.

RELEASE OF CHEMICAL FROM USE

Up to 2% of the annual import volume may be disposed of to landfill as off-specification manufactured articles containing the notified polymer. However, during the manufacture of articles, the notified polymer is expected to be consumed and irreversibly incorporated within a polyurethane polymer matrix. Therefore, significant release of the notified polymer to the environment is not expected.

RELEASE OF CHEMICAL FROM DISPOSAL

Manufactured articles containing the notified polymer are expected to remain in the environment. However, given the consumed/entrapped nature of the notified polymer, significant environmental exposure is not expected.

7.1.2 Environmental fate

The notified polymer was found to meet the criteria for ready biodegradability, achieving 78% degradation in 28 days, and 45% degradation within a 10-day window. For the details of the environmental fate studies, refer to Appendix C. The reacted notified polymer within manufactured articles is expected to eventually degrade via biotic and abiotic process to form simple organic degradates.

7.1.3 Predicted Environmental Concentration (PEC)

Aquatic release of unreacted notified polymer is not expected at any point during its lifecycle within Australia. Therefore, it is not possible to predict an environmental concentration.

7.2. Environmental effects assessment

The results of ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of the Daphnia toxicity study can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (analogue)	LC50 >100 mg/L (WAF)	The analogue was not harmful to fish up to the limit of its solubility in water.
Daphnia Toxicity	EC50 = 43 mg/L	The notified polymer is harmful to aquatic invertebrates.
Algal Toxicity (analogue)	E_rC50 = 20.5 mg/L (WAF)	The analogue was found to be harmful to freshwater algae at the limit of its solubility in water.

While three ecotoxicity tests were submitted, only one (aquatic invertebrates) was performed using the notified polymer. However, due to the significant (~40×) difference in water solubility between the submitted analogue and the notified polymer, the submitted analogue was not considered to be sufficiently representative to be considered acceptable for the purposes of environment hazard evaluation.

7.2.1 Predicted No-Effect Concentration

Based on the single ecotoxicity endpoint derived for the notified polymer, and using a conservative safety factor of 1000, the Predicted No-Effect Concentration (PNEC) is 43 µg/L. If the endpoint derived for an analogue for algal toxicity is used with the conservative safety factor of 1000, the PNEC would be 20.5 µg/L.

7.3. Environmental risk assessment

As it is not possible to predict and environmental concentration (PEC) it is not possible to calculate a risk quotient. However, as release to the aquatic environment is not expected at any point in the lifecycle of the notified polymer within Australia, the risk of harm to aquatic organisms is correspondingly low. While articles manufactured using the notified polymer is expected to remain in the environment due to the nature of their use, the notified polymer is expected to be consumed during the manufacturing process. Therefore, the notified polymer is not expected to pose an unacceptable risk to the Australian environment from the proposed use pattern and volume.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

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

	Hazard category	***Hazard statement***
Environment	Acute Category 3	Harmful to aquatic organisms

Human health risk assessment

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

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

Environmental risk assessment

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practice to minimise occupational exposure during handling of the notified polymer as introduced in product Sovermol 1102:
  - Avoid contact with the eyes

  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 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(2) of the Act; if
- the function or use of the chemical has changed from manufacturing of polyurethanes adhesives for construction and civil engineering, or is likely to change significantly;
- the amount of chemical being introduced has increased from 100 tonnes, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point Between -19°C and 5°C

TEST SUBTSANCE	Notified polymer
METHOD	OECD TG 102 Melting Point/Melting Range.
Remarks	The freezing point was determined using differential scanning calorimetry.
TEST FACILITY	Henkel AG & Co. KGaA (2009a)

Boiling Point > 298°C at 101.3 kPa

TEST SUBTSANCE	Notified polymer
Method	OECD TG 103 Boiling Point.
Remarks	The differential scanning calorimetry method was employed.
TEST FACILITY	Henkel AG & Co. KGaA (2009b)

Density 969 kg/m^3 at 20°C

TEST SUBTSANCE	Notified polymer
METHOD	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using the pycnometer method.
Test Facility	Henkel AG & Co. KGaA (2009c)

Viscosity 800-1,400 mpa.s at 20°C

METHOD	DIN 53015-78 (Hoeppler method)
Remarks	Test report not provided. Value was quoted in the product MSDS.

Vapour Pressure $\leq 0.006 \times 10^{-3}$ kPa at 20°C

TEST SUBTSANCE	Notified polymer
METHOD	OECD TG 104 Vapour Pressure.
Remarks	The differential scanning calorimetry method was employed.
TEST FACILITY	Henkel AG & Co. KGaA (2009d)

Water Solubility 0.22 g/L at 20°C

Method	EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method, with HPLC analysis.
Test Facility	Henkel AG & Co. KGaA (2009e)

Partition Coefficient (n-octanol/water) log Pow >5.7 at 20°C

Method	EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	HPLC Method. The notified polymer eluted after the reference substance triphenylamine.
Test Facility	Henkel AG & Co. KGaA (2009f)

Flash Point 212°C at 101 kPa

METHOD	ISO 2592
Remarks	Test report not provided. Value was given in the product MSDS.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Analogue 1

METHOD: OECD TG 401 Acute Oral Toxicity – Limit Test.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.

Species/Strain	Rat/Wistar
Vehicle	Peanut oil
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 (M)	2000	0
2	5 (F)	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	The male animals did not show any signs of toxicity for the duration of the study (14 days). However, one female animal had slightly reddish coloured nose after 4-24 hours. No further symptoms were observed up to 14 days.
Effects in Organs	No special finding was noticed in male animals. In female animals, one animal had hydrometra, which was not thought to be test-substance related.
Remarks - Results	All animals gained weight by the end of the study (Day 14). However, weight gain was more pronounced in male animals.

CONCLUSION: The notified polymer is of low toxicity via the oral route.

TEST FACILITY: Institute for Toxicology (1989a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Analogue 2

METHOD: EC Directive 79/831/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain	Rat/Sprague-Dawley
Vehicle	None
Type of dressing	occlusive
Remarks - Method	Only the summary of the test report was provided in English and details of any protocol deviations are not available. Five rats per sex were tested at one dose level.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 M / 5 F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No signs of local toxicity were observed.
Signs of Toxicity - Systemic	No signs of systemic toxicity were observed.
Effects in Organs	No pathological findings.

CONCLUSION The test substance is of low toxicity via the dermal route.

TEST FACILITY Henkel KGaA (1985a)

B.3. Irritation – skin

TEST SUBSTANCE Analogue 1

METHOD
- Species/Strain: Rabbit/Small Russian
- Number of Animals: 3 M
- Vehicle: None (test substance was liquefied by heating to 37ºC)
- Observation Period: 72 hours
- Type of Dressing: Semi-occlusive.
- Remarks - Method: No significant protocol deviations. A dose of 0.5 mL of the undiluted test substance was applied to each application site for four hours.

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	0	0	0	0	0	0
Oedema	0	0	0	0	0	0

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

Remarks - Results All animals showed no signs of any symptoms during the observation period of 72 hrs.

CONCLUSION The notified polymer is non-irritating to the skin.

TEST FACILITY Institute for Toxicology (1989b)

B.4. Irritation – eye

TEST SUBSTANCE Analogue 1

METHOD
- Species/Strain: Rabbit/Small Russian
- Number of Animals: 3
- Observation Period: 72 hours
- Remarks - Method: No significant protocol deviations. A dose of 0.1 mL of the undiluted test substance was applied to the conjunctival sac of the right eye of each rabbit.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect***	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.67	0.33	0.67	2	24 hours	0
Conjunctiva: chemosis	0.33	0	0.33	1	24 hours	0
Conjunctiva: discharge	0.33	0	0.33	3	24 hours	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
**Redness, chemosis and discharge effects were noted at 24 hours and were absent at 48 hours.

Remarks - Results	All three animals showed slight conjunctival reddening and swelling up to the 24-hour evaluation.
CONCLUSION	The notified polymer is slightly irritating to the eye.
TEST FACILITY	Institute for Toxicology (1989c)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Sovermol 1102
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay Plate Incorporation Method –Experiment I Pre-Incubation Method – Experiment II
Species/Strain	Mouse/CBA/CaOlaHsd, female
Vehicle	Acetone:oliveoil (4+1)
Remarks - Method	No significant protocol deviations. To determine the highest non-irritant and technically applicable test item concentration, a non-GLP pretest was performed in two mice with concentrations of 6.25, 12.5, 25 and 50% (w/v). The test substance in the main study was assayed at three consecutive concentrations (12.5, 25 and 50%). The top dose is the highest technically achievable concentration whilst avoiding systemic toxicity and excessive local irritation.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	1109.8	1.00
12.5	1311.2	1.18
25	1495.0	1.35
50	1658.1	1.49
Positive Control (α-Hexylcinnamaldehyde)		
5	820.1	1.05
10	1343.8	1.71
25	2587.8	3.30

Remarks - Results	No symptoms of local toxicity at the ears of the animals and no systemic findings were observed during the study period. No deaths occurred during the study period. The EC3 value could not be calculated as all stimulation indexes were below 3.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.
TEST FACILITY	RCC (2005)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Analogue 2
METHOD	EC Directive 79/831/EEC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week

	Satellite group: 24 days exposure, followed by 28 days recovery.
Vehicle	1% aqueous carboxymethylcellulose/0.5% cremophore
Remarks - Method	Deviations from the protocol: - Urinalysis was not conducted; - Haematology: platelet count and thromboplastin time were not determined; - Clinical chemistry: albumin was not measured.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10 M & 10 F	0	0
II (low dose)	10 M & 10 F	100	0
III (mid dose)	10 M & 10 F	500	0
IV (high dose)	10 M & 10 F	1000	1
V (control recovery)	5 M & 5 F	0	0
VI (high dose recovery)	5 M & 5 F	1000	0

Mortality and Time to Death

One male in the high dose group died during the eye examination at the end of the study. This was not considered to be treatment-related.

Clinical Observations

Salivation was observed in some male and female animals at the highest dose. Variations in food and water consumption as well as body weight gain were observed, but none of these were considered to have test substance or dose related relevance.

Laboratory Findings

Clinical Chemistry

Increases in alanine aminotransferase levels were observed for each dose group. The increase was dosage-dependent, with clear and significant increases observed for the high dose group.

Haematology

Slightly decreased haematocrit and clearly decreased erythrocyte values were observed in male and female animals of the mid dose group, as well as male animals of the high dose group.

Effects in Organs

A significant increase in the relative liver weights was observed for male and female animals of the high dose group.

Macroscopic examination did not reveal any compound related damage to the organs in any of the treated animals.

Microscopic examination revealed degenerative alterations in the kidneys of animals of the high dose group. These were reversible in the recovery group.

Remarks – Results

Daily administration of 1000 mg/kg bw of the test substance is a cumulative toxic level for rats. The target organs are liver and kidney. Daily administration of 500 mg/kg bw of the test substance leads to minor variations of some haematological values.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 100 mg/kg bw/day in this study, based on liver and kidney effects seen at 1000 mg/kg bw, and the variations seen in the haematological values at 500 mg/kg bw.

TEST FACILITY Institute for Toxicology (1987)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE	Sovermol 1102
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with phenobarbital/5,6-benzoflavone
Concentration Range in Main Test	a) With metabolic activation: 33, 100, 333, 1000, 2500, 5000 µg/plate b) Without metabolic activation: 33, 100, 333, 1000, 2500, 5000 µg/plate
Vehicle	DMSO
Remarks - Method	No significant protocol deviations. In the pre-experiment, the concentration range of the test substance was 3, 10, 33, 100, 333, 1000, 2500, and 5000 µg/plate, with and without metabolic activation. The pre-experiment is reported here as experiment 1. Since no toxic effects were observed in experiment 1, 5000 µg/plate were chosen as maximal concentration in experiment II and the concentration range was 33, 100, 333, 1000, 2500 and 5000 µg/plate. The test substance precipitated at 5000 µg/plate. In the overlay agar in both experiments with and without metabolic activation. The undissolved particles of the test item had no influence on the data recording.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	Not performed	5000	Negative
Test 2	Not performed	>5000	5000	Negative
Present				
Test 1	>5000	Not performed	5000	Negative
Test 2	Not performed	>5000	5000	Negative

Remarks - Results	In the two main tests, neither an increase in the number of revertant colonies or a dose-related response was observed with or without metabolic activation. The positive controls showed a distinct increase in induced in revertant colonies.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	RCC (2006)

B.8. Genotoxicity – in vivo

TEST SUBSTANCE	Analogue 2
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Albino mice/ CFW 1
Route of Administration	Oral – gavage
Vehicle	2% aqueous carboxymethylcellulose/0.5% cremophore
Remarks - Method	The full study report was only provided in German. Only 1000 PCE in each sample were examined for the presence of micronuclei. The samples from animals dosed at 1000 and 5000 mg/kg were not evaluated as the high dose samples were negative for clastogenicity.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	7 M & 7 F	0	24
II (low dose)	7 M & 7 F	1000	24
III (mid dose)	7 M & 7 F	5000	24
IV (high dose)	7 M & 7 F per sacrifice time	10,000	24, 48 & 72
V (positive control, CP)	7 M & 7 F	10	24

CP=cyclophosphamide. .

RESULTS

Doses Producing Toxicity	The highest dose used (10,000 mg/kg bw) produced toxicity (reduced activity and ruffled fur) but did not produce mortalities.
Genotoxic Effects	The test substance did not induce a statistically significant increase in the frequency of micronucleated PCE over the levels observed in the vehicle control.
Remarks - Results	The test substance is considered negative in this micronucleus assay. The frequency of micronucleated PCE in the positive control was significantly higher than the vehicle control.

CONCLUSION The test substance was not clastogenic under the conditions of this in vivo mouse micronucleus assay.

TEST FACILITY Institute for Toxicology (1985)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ultimate biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 F Ultimate Biodegradability: Manometric Respirometry Test.
Inoculum	Municipal sewage
Exposure Period	28 days
Auxiliary Solvent	Water
Analytical Monitoring	Oxygen consumption / DOC
Remarks - Method	No significant protocol deviations were reported.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	39	7	75
14	59	14	85
21	73	21	87
28	78	28	87

Remarks - Results	Additional substance specific analysis was done in accordance to note 3 at the MITI guidance document for testing the biodegradability of chemical substances by micro-organisms, to identify the degradation products and intermediates. According to the derivation procedure described in the annex 'analytical determination of Sovermol 1102' all alcoholic hydroxylgroups were derivated to the corresponding trimethylsilyl (TMS) ethers, which can directly be separated by gas chromatography. It could be shown that in contrast to the good recovery rate of the notified polymer at the test start, neither the hydrophobic parent-substances nor other hydrophobic compounds were traceable in the final samples. Only one of three parallel flasks showed small remains (<2%) of the notified polymer. In order to determine polar metabolites, further investigations were made. Although it was not possible to identify the exact structure of these substances, their high polarity and their low molecular weight are indicative for them being degradation products. Thus the notified polymer appears to have been almost completely mineralised, respectively fixed in biomass within the examined test period of 28 days.
CONCLUSION	The notified polymer is ultimately biodegradable.
TEST FACILITY	Henkel KGaA (1997)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Water Hardness	267 mg $CaCO_3$/L

Analytical Monitoring	DOC
Remarks - Method	Due to the poor water solubility of the notified polymer, the test was conducted using Water Accommodated Fractions (WAF).

RESULTS

Concentration mg/L		*Number of D. magna*	*% Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		25	0	0
1		25	0	0
3		25	0	0
10		25	0	0
30		25	8	8
100		25	80	100

LC50	43 mg/L at 48 hours (95% C.I. = 34 – 53) WAF
NOEC	10 mg/L at 48 hours WAF
Remarks - Results	All validation criteria were satisfied. As the notified polymer was found to be stable, the EC value given in this report was based on the nominal concentrations.

CONCLUSION The notified polymer is harmful to *Daphnia magna*.

TEST FACILITY Evonik Stockhausen GmbH (2009)

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