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

FULL PUBLIC REPORT

Sovermol 750

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 and Water Resources.

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
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FULL PUBLIC REPORT**Sovermol 750****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Cognis Australia Pty Ltd (ABN 87 006 374 456)
4 Saligna Drive
Tullamarine VIC 3047

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 name, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Spectral Data, Purity, Identity of Impurities/Residual Monomers, Import Volume, Identity of Formulation Sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Hydrolysis, Partition Coefficient, Absorption/Desorption, Dissociation Constant, Autoignition Temperature, Acute Oral Toxicity, Acute Dermal Toxicity, Skin Irritation, Eye Irritation, Skin Sensitisation, Induction of Point Mutations, Chromosome Damage, Fish Acute Toxicity, Daphnia sp. Acute Immobilisation/Reproduction.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA – PMN 1994

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Sovermol 750

MOLECULAR WEIGHT

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

ANALYTICAL DATA

Reference IR, GC, and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 98%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

None.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Yellow liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Between -10°C and 6°C	Measured
Boiling Point	> 200°C at 101.3 kPa	Measured
Density	980-1020 kg/m ³ at 20°C	MSDS
Viscosity	800-1,400 mpa.s	MSDS
Vapour Pressure	1.6 × 10 ⁻³ kPa at 25°C	Measured
Water Solubility	5.23 mg/L at 20°C	Measured
Hydrolysis as a Function of pH	Unlikely to hydrolyse at the environmental pH of 4-9	Not measured
Partition Coefficient (n-octanol/water)	log Pow = 5.67 (major component 1)	Calculated (EPIWIN)
	log Pow = 12.16 (major component 2)	Calculated (EPIWIN)
Adsorption/Desorption	log K _{oc} = 2.97 (major component 1)	Calculated (EPIWIN)
	log K _{oc} = 6.11 (major component 2)	Calculated (EPIWIN)
Dissociation Constant	No dissociable groups present in the notified chemical	Not measured
Particle Size	Not applicable	Notified chemical is a liquid
Flash Point	202°C at 101 kPa	MSDS
Flammability	Not determined.	Based on the flash point of the chemical it would be expected to have limited flammability.
Autoignition Temperature	Not determined	The notified chemical is not expected to autoignite under normal conditions of use.
Explosive Properties	Not expected to be explosive	Estimated

Discussion of Observed Effects

For full details of the physical-chemical properties tests please refer to Appendix A.

Reactivity

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

Dangerous Goods classification

Based on the available physico-chemical properties the notified chemical is not classified as a Dangerous Good according to the Australian Dangerous Goods Code (FORS, 1998). However, based on the flash point the notified chemical is a C2 combustible liquid.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical is imported into Australia as the product Sovermol 750.

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

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

PORT OF ENTRY

Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

Currently only one customer site (formulator) identified in Sydney metropolitan area of NSW.

TRANSPORTATION AND PACKAGING

The notified chemical will be brought in by ship in either 20 L or 200 L plastic lined steel drums.

Waterside workers will transfer the containers from the ship to a truck for road transport to the formulator site.

The finished coating products will be packaged and sold in 1, 2, 4, 10 and 20 L cans, which will be transported by road from the formulator site to customers.

USE

The notified chemical will be imported as an ingredient for use in industrial surface coatings.

Sovermol 750 branched polyol which, when combined with modified or polymeric MDI (Methylene Diphenyl Diisocyanate) can be used for two-part chemical resistant coatings. Sovermol 750 may also be cured with aliphatic isocyanates to produce light stable coatings.

OPERATION DESCRIPTION

Coating formulation

At the coating formulation facility drums containing the notified chemical are fitted with taps and a hydraulic drum lifter is used to decant the notified chemical into a stainless steel enclosed blending vessel. The notified chemical is blended with other ingredients, including pigments and then samples are taken for quality assurance. Once approval is given the coating mixture is filtered and filled into epoxy lined paint cans for distribution. The formulation facility has local and general ventilation in use.

End-use

During end-use the coating formulation containing the notified chemical (50-70%) is supplied as Part A of a two component paint, where Part B contains a polyisocyanate. Parts A and B are mixed manually before application. The combined product is then applied to the floor by roller application and left to cure and harden. At this stage the notified chemical is reacted into the coating. After application the used roller sleeves are allowed to harden/cure and are disposed of in industrial solid waste.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Formulation operator	15	4-6 hours/day	50-200 days/year
QA Laboratory technician	6	4-6 hours/day	50-200 days/year
Maintenance	3	0.5 hours/day	10-50 days/year
End-Use	40	5 hours/day	50 days/year

Exposure Details

Coating Formulation

Inhalation exposure is not expected as the notified chemical is a liquid with a low vapour pressure. Dermal and accidental ocular exposure may occur during formulation processes such as decanting the notified chemical into the mixer, sampling and testing for quality assurance, cleaning and maintenance. Due to the enclosed nature of the blending process and the method used for decanting the drums, the greatest potential for exposure is expected to occur during sampling and testing for quality assurance. Exposure is expected to be minimised by the use of engineering controls, such as ventilation, as well as the use of personal protective equipment (PPE) such as overalls, safety glasses and chemical resistant gloves.

According to EASE (1997) modelling of this work environment, in which it is assumed that incidental, non-dispersive use occurs with direct handling, dermal exposure is estimated to be in the range 0-0.1

mg/cm²/day. Assuming 100% dermal absorption, a surface area of 420 cm² (half the total area of both hands), and a bodyweight of 70 kg this equates to a systemic exposure of 0-0.6 mg/kg bw/day. The model is a conservative one and may overestimate exposure. The model does not take into account the duration of the activity and the use of PPE and ventilation.

End-use

Dermal and accidental ocular exposure to the paint formulation containing the notified chemical (50-70%) may occur due to drips, spills and splashes during the mixing of the floor coating and the application of the paint by roller. PPE usage is determined by the polyisocyanate used and typically consists of chemical resistant gloves, safety glasses, overalls and respirators in accordance with AS/NZS 1716.

According to EASE (1997) modelling of this work environment, in which it is assumed that intermittent, non-dispersive use occurs with direct handling, dermal exposure is estimated to be in the range 0.1-1 mg/cm²/day. Assuming 100% dermal absorption, a surface area of 420 cm² (half the total area of both hands), a concentration of 50-70% in the paint and a bodyweight of 70 kg this equates to a systemic exposure of 0.3-4.2 mg/kg bw/day. The model is a conservative one and may overestimate exposure. The model does not take into account the duration of the activity, the use of PPE, and the fact that after mixing the concentration of the notified chemical in the paint mix actually applied is reduced. In addition dermal absorption is expected to be < 100%.

6.1.2. Public exposure

The notified chemical, and formulated paint products containing the notified chemical are not intended to be used by the public. The public may come into contact with floors coated with the paint containing the notified chemical, however at this stage the notified chemical is reacted into the cured coating and is therefore not bioavailable.

6.2. Human health effects assessment

No toxicological investigations have been conducted on the notified chemical. Analogue data has been provided for LA990 and Sovermol 760, which are structurally related reaction mixtures. The results from these toxicity studies are considered to predict the likely toxicity of the notified chemical and are summarised in the table below. Details of these studies can be found in Appendix B.

<i>Endpoint</i>	<i>Analogue</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LA990	oral LD50 > 5000 mg/kg bw low toxicity
Rat, acute dermal toxicity	LA990	LD50 > 2000 mg/kg bw low toxicity
Rat, acute inhalation toxicity	-	not determined
Rabbit, skin irritation	Sovermol 760	moderately irritating
Rabbit, eye irritation	Sovermol 760	slightly irritating
Guinea pig, skin sensitisation –non-adjuvant test.	Sovermol 760	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	LA990	NOAEL = 100 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	Sovermol 760	non mutagenic
Genotoxicity – in vivo mouse micronucleus test	LA990	non genotoxic

Toxicokinetics

No toxicokinetic studies were submitted. The major components of the reaction mixture have molecular weights of less than 1000, so dermal absorption is possible. However, based on the predicted high partition coefficients and the lack of systemic effects in the acute dermal toxicity study, dermal absorption of the notified chemical is expected to be limited.

Acute toxicity

The analogue chemical LA990 was found to be of low acute toxicity via both the oral and dermal exposure routes in tests on the rat.

Irritation and Sensitisation

A primary dermal irritation study in the rabbit showed that the analogue chemical Sovermol 760 is moderately irritating to the skin, with varying degrees of erythema seen in all animals up to 72

hours after exposure. In an eye irritation study in the rabbit the analogue chemical Sovermol 760 was shown to be slightly irritating, causing mild to moderate irritation of the conjunctivae. A skin sensitisation test in guinea pigs conducted using the analogue chemical Sovermol 760 showed no evidence of reactions indicative of sensitisation.

Repeat dose toxicity

In a 28 day subacute oral toxicity study in rats evidence of toxicity of the analogue chemical LA990 was observed at 1000 mg/kg bw/day, including 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). 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 liver and kidney effects seen at 1000 mg/kg bw, and the variations seen in the haematological values at 500 mg/kg bw.

Genotoxicity

The analogue chemical Sovermol 760 was not mutagenic to *S. Typhimurium* in a Bacterial Reverse Mutation Test with or without metabolic activation. In an *in vivo* micronucleus test in the mouse the analogue chemical LA990 was found to be non-clastogenic. The notified chemical is therefore not expected to be a mutagen or genotoxin.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Coating Formulation

During the formulation processes dermal exposure for workers is estimated to be 0-0.6 mg/kg bw/day. A dermal NOAEL was not determined, however a NOAEL of 100 mg/kg bw/day was established in a 28-day oral study in the rat. The use of this NOAEL results in a margin of exposure (MOE) > 167. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. The MOE is based on conservative assumptions and may overestimate the risk. Therefore, the risk of systemic effects to workers during coating formulation is considered acceptable.

However, due to the skin and eye irritancy potential of the notified chemical protective gloves and eyewear should be worn during all processes where dermal and ocular exposure is possible.

End-use

Dermal exposure to workers involved in using the coating formulation containing the notified chemical may occur during the mixing of the floor coating and the application of the paint by roller. The dermal exposure for these workers when adequate PPE is used is estimated to be 0.3-4.2 mg/kg bw/day. Using the oral NOAEL, as above, results in a margin of exposure (MOE) of 24-333. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore the risk of systemic effects may not be acceptable for workers involved in the application of the coating formulation. However the MOE is based on conservative assumptions, including no PPE usage and 100% dermal absorption, and may overestimate the risk. The PPE usage during handling and application of the coating is determined by the hazardous nature of the other component of the paint mix (polyisocyanate) and is expected to minimise the worker exposure to the notified chemical as well. Therefore the risk of systemic effects to workers during use of the coating formulation is considered acceptable with the described use of PPE.

Due to the skin and eye irritancy potential of the notified chemical protective gloves and eyewear should be worn during mixing of the floor coating and the application of the paint by roller.

6.3.2. Public health

The risk to public health is considered to be low based on the minimal public exposure to the notified chemical.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported in either 20 L or 200 L plastic lined steel drums and thus there is no environmental exposure associated with the manufacturing process. It will be used as an additive for coating formulations.

During the blending of the end use coating, the drums are decanted into the mixing vessel using a hydraulic drum lifter. The blending facility is generally enclosed and environmental exposure via spills or leaks is minimised. In addition the absence of solvent in the coating process would further minimise the vapourisation of the notified chemical. In case of a spill, liquid absorbing material (sand, peat, sawdust) will be used to absorb liquid spills and be disposed of to landfill. The imported drums will be thoroughly drained and rinsed with a process fluid (eg plasticiser) which will be added to the coatings being prepared. It is estimated that residues in a rinsed drum would contain less than 100 mL of rinsing that would contain <50 mL (0.25%) of the notified chemical per 200 L drum. The rinsed drums are expected to be sent to a drum recycling facility. The coating is filtered and filled into epoxy lined paint cans of 1, 2, 4, 10 and 20 L sizes. If changing to an incompatible product, blending and packaging equipment would be cleaned using minimal quantities of hydrocarbon solvents which are collected in 200 L drums disposed of via a licensed solvent recycling/waste management company.

RELEASE OF CHEMICAL FROM USE

The product will be restricted to industrially applied self-levelling flooring and there will be no DIY or domestic use. The product is part of a 2 part mix and is applied by roller coating which cures with aliphatic isocyanates on the surface of the object being coated without the application of heat. There is minimum exposure during this process as no overspray is generated. Used roller sleeves are allowed to harden/cure and be disposed of as articles in industrial solid waste. Application equipment cleaning materials will be disposed of with specific liquid waste via accredited contractor. Any excess liquid after blending with hardener would be sent for landfill after product has been cured and dried. Well drained end use product containers would be recycled or in the case of small containers, placed in landfill rubbish.

Release to water is expected to be negligible, and releases on land are likely to be restricted in landfill, and in a fairly dispersed manner throughout the life of the products coated with the notified chemical.

RELEASE OF CHEMICAL FROM DISPOSAL

Any waste product would be sent for landfill after product has been cured and dried. The waste product can also be incinerated with the approval of local authority.

7.1.2 Environmental fate

The notified polymer contains ester linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur. Its relatively low water solubility and likely hydrophobic nature are indicative of

partitioning into the octanol phase and the notified chemical's immobility in soil. On the basis of the biodegradation studies, the notified chemical is not considered to be readily biodegradable.

Based on the calculated BCF value, the relatively low molecular weight and the calculated high log Kow values of >5 for both major reaction components, the notified chemical is considered to be potentially bioaccumulative. However, release to aqueous compartment will be very low and it was shown to be partly degradable in standard ready biodegradability tests.

For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

Under the proposed use pattern, the exposure to the aquatic compartment is likely to be very low. Therefore, a PEC calculation was not performed.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical and an analogue chemical are summarised in the table below. Details of these studies can be found in Appendix C.

<i>Endpoint</i>	<i>Test Substance</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	Sovermol 760	96 h LC50 >100 mg/L WAF	The notified chemical shows some toxicity to fish
Algal Toxicity	Notified chemical	72 h EbC50 = 5.93 mg/L 72 h ErC50 = 20.5 mg/L	The notified chemical is harmful to alga

On the basis of ecotoxicity data provided, the toxicological end point would be 72 h ErC50 of 20.5 mg/L for alga.

7.2.1 Predicted No-Effect Concentration

The PNEC is 20.5 µg/L, using a safety factor of 1000 since toxicity data are available for two trophic levels only and the acute 72 h ErC50 of 20.5 mg/L for alga.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ErC50 (72 h) alga	20.5	mg/L
Assessment Factor	1000	
Mitigation Factor	1.00	
PNEC:	20.5	µg/L

7.3. Environmental risk assessment

The majority of the notified chemical will be cured on floor surface after roller coating and thus minimal environmental exposure is likely to occur. The fate of the notified chemical will likely be a disposal to landfill with the cured products at the end of its useful lives.

Waste generated during the blending and flooring process will either be landfilled or incinerated generating water vapour and carbon dioxide. The likely route of environmental exposure is from accidental spillage and the washing of the used import container. In case of spillage, it would be contained to the plant by bunding during the blending process. The residues from the washings would either be recycled or be disposed of by waste contractors.

If spilled on land or in landfill, the notified chemical is expected to become immobilised in the soil layer and be degraded by the abiotic and biotic processes.

The very limited exposure of the notified chemical to the aquatic compartment due to its industrial settings is unlikely to have an adverse effect on the aquatic organisms.

Given its limited environmental exposure, the notified chemical is unlikely to pose an environmental risk under the proposed use pattern.

8. CONCLUSIONS – SUMMARY OF RISK ASSESSMENT FOR THE ENVIRONMENT AND HUMAN HEALTH

8.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the classification of notified chemical 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.

	<i>Hazard category</i>	<i>Hazard statement</i>
Environment	Chronic 3	The notified chemical is harmful to alga

8.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

8.3. Human health risk assessment

8.3.1. Occupational health and safety

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

8.3.2. Public health

When used in the proposed manner the risk to the public is considered to be acceptable.

9. MATERIAL SAFETY DATA SHEET

The MSDS of the product Sovermol 750 provided by the notifier was reviewed by NICNAS and is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant. The MSDS requires the following amendments:

- The contact details for the Australian supplier, including an emergency phone number must be added to Section 1;
- The statement 'Not classified as hazardous according to the criteria of NOHSC' must be added to Section 2

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced, and in the coating formulation:

- Avoid eye contact
- Avoid skin contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced, and in the coating formulation:
 - Protective eyewear
 - Impervious gloves
 - Protective clothing

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 chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of by landfill or incineration.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by removing it with liquid-absorbing material (sand, peat and sawdust) and be incinerated with the approval of a local authority.

11. REGULATORY OBLIGATIONS

This risk assessment is based on the information available at the time of notification. If the circumstances under which the notified chemical was assessed change a reassessment may be needed. Under 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 Chemicals Notification and Assessment 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 industrial surface coatings, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 10 tonnes, or is likely to increase, significantly;
 - if 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.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

Melting Point/Freezing Point		Between -10°C and 6°C
METHOD	In-house method	
Remarks	The freezing point was determined using differential scanning calorimetry. The test laboratory indicated that the sample was not easy to crystallise.	
TEST FACILITY	Henkel KGaA (1996b)	
Boiling Point		> 200°C at 101.3 kPa
METHOD	In-house method	
Remarks	The boiling point was determined using differential scanning calorimetry, and is given as a range as thermal decomposition of the sample occurred.	
TEST FACILITY	Henkel (1996b)	
Density		980-1020 kg/m ³ at 20°C
METHOD	DGF C-IV 2B (52)	
Remarks	Test report not provided. Value was quoted in the product MSDS.	
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		1.6 × 10 ⁻³ kPa at 25°C
METHOD	In-house method	
Remarks	The vapour pressure was determined using differential scanning calorimetry and thermogravimetric analysis. The value given is for the component of the mixture with the lowest boiling range (from the thermogravimetric analysis this is approximately <20% of the mixture). The main component has a higher vapour pressure.	
TEST FACILITY	Henkel (1996b)	
Water Solubility		5.23 mg/L at 20°C and pH of 7.48
METHOD	OECD TG 105 Water Solubility.	
Remarks	EC Directive 92/69/EEC A.6 Water Solubility. Approximately 25 mg of the notified chemical was weighed out in a flask with 50 mL of water in triplicate. The test mixtures were preincubated at 30°C with constant stirring. After 24, 48 and 72 h preincubation the flasks were kept at a temperature of 20°C. Due to the inhomogeneous solubility results, the preincubation was prolonged from 72 to 120 h. Samples were taken 24 h after transfer to the test temperature and analysed by LC-MS/MS.	
TEST FACILITY	The notifier has also provided EPIWIN calculations for both the major components of the reaction mixture. The water solubility at 25°C was calculated to be 0.31 and 3.28 X 10 ⁻⁸ mg/L for major component 1 and 2, respectively. Dr U Noack-Laboratorien (2006a)	
Hydrolysis as a Function of pH		Not measured
Remarks	Though it contains a hydrolysable ester, the notified chemical is unlikely to hydrolyse at the environmental pH range of 4-9 due to its relatively low water solubility.	

Partition Coefficient (n-octanol/water) Not measured

METHOD	KOWWIN Program (v1.67)
Remarks	Estimated log Kow by EPI suite to be 5.67 and 12.16 for major component 1 and 2, respectively.

Adsorption/Desorption Not measured

METHOD	PCKOCWIN Program (v1.66)
Remarks	Estimated Koc using PCKOCWIN program to be 946.6 and 1,293,000 (log Koc = 2.98 and 6.11, respectively) for major component 1 and 2, respectively.

Dissociation Constant Not applicable

Remarks	The notified chemical does not contain any dissociable groups and thus it is not expected to dissociate under the environmental pH of 4-9.
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Flash Point 202°C at 101 kPa

METHOD	DIN ISO 2592-81
Remarks	Test report not provided. Value was given in the product MSDS.

Explosive Properties Not expected to be explosive

METHOD	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	The notified chemical contains no functional groups that would infer explosive properties.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	LA990
METHOD	EC Directive 79/831/EWG B.1 Acute Toxicity (Oral)-Limit test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	1% aqueous carboxymethylcellulose/0.5% cremophore
Remarks - Method	Only the summary of the test report was provided in English, therefore protocol deviations can not be determined. Five rats per sex were tested at one dose level.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5 M / 5 F	5000	0

LD50	> 5000 mg/kg bw
Signs of Toxicity	Piloerection and diarrhoea were observed in all animals between 2 and 8 hours after dosing.
Effects in Organs	None

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

TEST FACILITY Henkel (1985a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	LA990
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, therefore protocol deviations can not be determined. Five rats per sex were tested at one dose level.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
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 (1985b)

B.3. Acute toxicity – inhalation

Not conducted.

B.4. Irritation – skin

TEST SUBSTANCE	Sovermol 760 (90% purity)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test substance administered as supplied
Observation Period	8 days
Type of Dressing	Semi-occlusive.
Remarks - Method	The test article was stored at room temperature, rather than refrigerated as the latter was inappropriate. No significant protocol deviations. GLP Compliant.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	<i>Animal No.</i>					
	1	2	3			
<i>Erythema/Eschar</i>	1.67	2.00	1.33	2	< 8 days	0
<i>Oedema</i>	0.67	0.67	0.67	1	<72 hours	0

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

Remarks - Results	Well-defined to very slight erythema and very slight oedema were observed in all animals 1 hour after the end of the exposure. Erythema was still apparent in all animals until 72 hours after exposure and in one animal (No.3) up to day 7 after exposure.
CONCLUSION	The test substance is moderately irritating to the skin.
TEST FACILITY	ToxLabs BioScience GmbH (1998a)

B.5. Irritation – eye

TEST SUBSTANCE	Sovermol 760 (90% purity)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	The test article was stored at room temperature, rather than refrigerated as the latter was inappropriate. No significant protocol deviations. GLP Compliant.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>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>Conjunctiva: redness</i>	0.33	0.33	0.67	2	< 72 hours	0
<i>Conjunctiva: chemosis</i>	0.33	0.33	0.33	2	< 48 hours	0
<i>Conjunctiva: discharge</i>	-	-	-	-	-	0
<i>Corneal opacity</i>	0**	0	0**	0	-	0
<i>Iridial inflammation</i>	0	0	0	0	-	0

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

** Slight vascular injection on the eyeball observed 1 hour after instillation.

Remarks - Results	Slight to moderate redness and swelling of the conjunctivae associated with slight ocular secretion were observed in all animals 1 hour after instillation. Slight redness and swelling were seen in all animals at 24 hours after instillation. Slight redness was apparent in one animal up to 48 hours after instillation. In two of the animals vascular injection on the eyeball was observed at 1 hour after instillation.
CONCLUSION	The test substance is slightly irritating to the eye.
TEST FACILITY	ToxLabs Bioscience GmbH (1998b)

B.6. Skin sensitisation

TEST SUBSTANCE	Sovermol 760 (90% purity)
METHOD	OECD TG 406 Skin Sensitisation – Buehler. EC Directive 96/54/EC B.6 Skin Sensitisation - Buehler.
Species/Strain	Guinea pig/pirbright white
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 25%
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: topical: 100%
Signs of Irritation	Slight erythema was seen in 4/20 animals after the first induction, 6/20 animals after the second induction and 12/20 animals after the third induction.
CHALLENGE PHASE	
1 st challenge	topical: 25%
Remarks - Method	The test article was stored at room temperature, rather than refrigerated as the latter was inappropriate. No significant protocol deviations. GLP Compliant.

RESULTS

Animal	Challenge Concentration	Number of Animals Showing Skin Reactions after:			
		1 st challenge		2 nd challenge	
		24 h	48 h	24 h	48 h
Test Group	25%	0	0	-	-
Control Group	25%	0	0	-	-

Remarks - Results	The test on the positive control alpha-hexyl cinnamic aldehyde proved the sensitivity of the test system and the reliability of the experimental technique.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.

TEST FACILITY ToxLabs Bioscience GmbH (1998c)

B.7. Repeat dose toxicity

TEST SUBSTANCE LA990

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

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
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 Henkel KGaA (1987)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Sovermol 760 (100% purity)

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 92/69/EC B.14 Salmonella typhimurium - Reverse Mutation Assay.
Plate incorporation procedure
Species/Strain *S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System S9 fraction from phenobarbital/beta-naphthoflavone induced rat liver
Concentration Range in Main Test a) With metabolic activation: 8, 40, 200, 1000 and 5000 µg/plate
b) Without metabolic activation: 8, 40, 200, 1000 and 5000 µg/plate
Vehicle Ethanol
Remarks - Method The strains used do not include *S. typhimurium*: TA102 or *E. coli* WP2 strains, which are recommended by the Guideline for detecting certain oxidising mutagens, cross-linking agents and hydrazines. The test substance is not considered to contain functional groups capable of oxidising or cross-linking and so the omission of these strains should not have a significant effect on the validity of the study. GLP Compliant.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test 1	-	> 5000	> 5000	negative
Test 2	-	> 5000	> 5000	negative
<i>Present</i>				
Test 1	-	> 5000	> 5000	negative
Test 2	-	> 5000	> 5000	negative

Remarks - Results The notified substance did not induce gene mutations in the strains of *S. typhimurium* either with or without metabolic activation. Positive controls confirmed the sensitivity of the test system.

CONCLUSION The test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Henkel KGaA (1999)

B.9. Genotoxicity – in vivo

TEST SUBSTANCE LA990

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.

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Sacrifice Time hours</i>
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

Henkel (1985c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test in accordance to note 3 at the MITI guidance document (identification of degradation products and intermediates)
Inoculum	Municipal sewage
Exposure Period	27 days
Auxiliary Solvent	None
Analytical Monitoring	BOD/COD/TOC
Remarks - Method	The test was performed under constant stirring in the Sapromat System. The degradation products and intermediates were identified by GC-MS after selective solvent extraction of the samples at the beginning and the end of the degradation test. Sodium acetate was used as the test reference. No details of the test procedure were provided.

RESULTS

<i>Test substance</i>		<i>Sodium acetate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
7	38	7	84
14	54	14	86
21	61	21	86
27	65	27	86

Remarks - Results

The results indicate that the notified chemical was 65% biodegraded within the test period of 27 days. However, the plateau for ready biodegradability was not reached for the 10 days window. However, derivatisation and GC showed the hydrophobic parent substances (both major reaction components) were completely biodegraded within the test period of 27 days and that only hydrophilic low molecular weight compounds were left.

Degradation in the reference substance reached >60% by day 7 indicating the validity of the test.

CONCLUSION

The notified chemical is not considered to be readily biodegradable under the strict conditions of the test.

TEST FACILITY

Henkel KGaA (1997a)

C.1.2. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test
Inoculum	Municipal sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	BOD/COD/TOC
Remarks - Method	The test was conducted at a nominal concentration of 100 mg/L. The test substance was introduced directly into the test system containing 300 mL nutrient medium per test flask. Biodegradation was evaluated by

measurement of the oxygen consumption in the test vessels. The biochemical oxygen was determined in the Sapromat system. The TOC analyses were performed at the start and end of the test. Sodium acetate was used as the test reference.

RESULTS

<i>Notified Chemical</i>		<i>Sodium acetate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
7	8	7	80
14	25	14	83
21	46	21	81
28	53	28	90

Remarks - Results

The results indicate that the notified chemical was 53% biodegraded by day 28 and thus ready biodegradation criterion was not met, consistent with the above test. Degradation in the reference substance reached >60% by day 4, indicating the validity of the test. The low solubility of the test substance resulted in differences in values between the DOC (90.1 mg/g) and the TOC (419 mg/g).

CONCLUSION

The notified chemical is not considered to be readily biodegradable.

TEST FACILITY

Henkel KGaA (1996c)

C.1.3. Ready biodegradability

TEST SUBSTANCE

Notified chemical

METHOD

BOD (biological oxygen demand) – test for Insoluble Substances (BODIS). Modified RDA/Blok Test. A repetitive die away (RDA) test combining several biodegradability test procedures (Blok 1979).

Inoculum

Mixed bacterial inoculum stabilised under laboratory conditions for one week

Exposure Period

28 days

Auxiliary Solvent

None

Analytical Monitoring

BOD

Remarks - Method

The test vessels were closed glass bottles with a known volume of aqueous test mixtures and air at a nominal test concentration of 100 mg/L. The bottles were shaken continuously to assure steady state oxygen partitioning between liquid and gas phase. The degradation was followed by weekly measurements of the BOD in the aqueous phase for 28 days. The total oxygen uptake in the flasks was calculated based on the measured DOC and the total oxygen content in the bottles.

RESULTS

<i>Notified Chemical</i>		<i>Sodium acetate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
7	55	7	71
14	74	14	81
21	83	21	82
28	86	28	84

Remarks - Results

The results appear to indicate that the notified chemical was readily biodegradable as it reached over 60% by day 14. Degradation in the reference substance reached >60% by day 7, indicating the validity of the test. However, due to the lack of details provided in the report, the results should be treated with caution.

CONCLUSION	It appears the notified chemical is readily biodegradable. However, the data should be treated with caution due to the lack of details in the report.
TEST FACILITY	Henkel KGaA (1991)

C.1.4. Bioaccumulation

Based on the calculated respective BCF values of 467.1 and 3.16 for the major components of the reaction mixture using BCF Program (v2.15), the relatively low molecular weights and the respective log Kow of 5.67 and 12.16 for major component 1 and 2, the notified chemical is considered to be potentially bioaccumulative. However, the notified chemical is potentially biodegradable and release to aqueous compartment is likely to be very low.

C.2. Ecotoxicological Investigations

Sovermol 760 was used as the analogue chemical for the notified chemical for toxicity test in fish. DEW considers the proposed analogue chemical to be acceptable.

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Sovermol 760
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi static conditions. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Semi static conditions
Species	Zebra barbel
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	None
Analytical Monitoring	GC
Remarks – Method	The fish were exposed to nominal concentrations of the test substance at 4.27, 9.39, 20.7, 45.5 and 100 mg/L for a period of 96 h. The test was carried out semi-statically, i.e. the test fish were transferred to a fresh preparation of the test substance every 24 h. The Water Accommodated Fractions (WAF) was prepared by allowing the mixture to stir for approximately 1 day and to stand for at least 2 h after stirring. The test solutions contained small droplets or particles. The aqueous phase was then separated off from the organic phase by filtration through a glass fibre filter previously treated with NaOH. The test solution concentrations were continuously aerated. The number of dead fish was counted immediately after placement of all fish (0 h) and after 2-4, 24, 48, 72 and 96 h. Temperatures, pH and DOC were measured during the course of the test. The test concentrations were measured by GC for the nominal concentrations of 20.7 and 100 mg/L

RESULTS

Concentration mg/L		Number of Fish	Mortality (%)				
Nominal	Actual		2-4 h	24 h	48 h	72 h	96 h
0		10	0	0	0	0	0
4.27		10	0	0	0	0	0
9.39		10	0	0	0	0	0
20.7	<0.5, 3.2 (0 h); <0.5 (24 h)	10	0	0	0	0	0
45.5		10	0	0	0	0	0
100	<0.5, 4.0, 4.4 (0 h); <0.5 (24 h)	10	0	0	10	10	10

LC50 >100 mg/L nominal WAF at 96 hours.

NOEC	45.5 mg/L nominal WAF at 96 hours.
Remarks – Results	10% mortality was observed at a nominal concentration of 100 mg/L at 48, 72 and 96 h. During the whole duration of the test the fish showed no signs of abnormal behaviour. A slight turbidity was observed at the highest test concentration. 3.2-4.4 mg/L were measured at the nominal test concentrations of 20.7 and 100 mg/L at 0 h but all <0.5 mg/L at 24 h. The water quality parameters (pH, temperatures and DOC) were within acceptable limits.
CONCLUSION	The test substance shows some toxicity to fish up to its limit of water solubility.
TEST FACILITY	Henkel KGaA (1997b)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	Freshwater green alga (<i>Desmodesmus subspicatus</i>)
Exposure Period	72 hours
Concentration Range	Nominal: 1.56 - 200mg/L Actual: 1.33 – 160 mg/L
Auxiliary Solvent	None
Water Hardness	0.24 mmol Ca+Mg/L
Analytical Monitoring	LC-MS/MS
Remarks - Method	The study was conducted under static conditions with an initial cell density of 10^3 – 10^4 cells/mL. Water accommodated fractions were prepared by shaking the dispersions in flasks for 24 h at 20°C. After phase separation (30 mins) the test medium was transferred from the homogeneous liquid phase to the test vessels. Nominal concentrations of 1.56, 3.13, 6.25, 12.5, 25, 50, 100 and 200 mg/L were used in the test. Three replicates were tested for each treatment concentration and six replicates for the control. The concentrations of the test substance were analysed at all concentrations at the start and end of the test using LC-MS/MS. Potassium dichromate was used as the reference item at the test concentrations of 0.1, 0.2, 0.4, 0.8, 1.6 and 3.2 mg/L. Cell density was measured via chlorophyll-a-fluorescence and cells were checked for any unusual cell shapes, colour differences, chloroplast morphology, flocculation, adherence of algae to test containers or aggregation of alga cells. After 72 h algae were transferred from nominal concentrations of 6.25-200 mg/L and control into untreated medium and allow growing for further 3 days for recovery test. When running a One Way Analysis of Variance, p values for both Normality and Equal Variance Tests were determined.

RESULTS

<i>Biomass</i>		<i>Growth</i>	
<i>EbC50</i> mg/L at 72 h	<i>NOEC</i> mg/L	<i>ErC50</i> mg/L at 72 h	<i>NOEC</i> mg/L
5.93 (CI: 5.23-6.73)	3.13	20.5 (CI: 16.6-25.3)	6.25

Remarks - Results	The test substance was found to inhibit the growth of alga at nominal
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concentrations of ≥ 6.25 mg/L (biomass growth) and ≥ 12.5 mg/L (growth rate). Microscopic evaluation of the cells at the start of the incubation period revealed no morphological abnormalities. At the end of the test the algae cells were partly agglutinated at 12.5 mg/L. Temperatures and pH were determined to be within acceptable limits. Initial concentrations of the test substance were in the range of 66-90% of the nominal concentrations. At the end of the 72 h exposure, the test substance could not be determined above LOQ of 0.5 mg/L. After 72 h of exposure at nominal concentrations of 6.25-200 mg/L, the effects of the test substance were observed to be reversible 3 days after 72 h exposure. Therefore, there is a potential for recovery following exposure up to 200 mg/L. The toxicity test for the reference substance gave an EbC50 and ErC50 of 0.31 and 0.56 mg/L, respectively, indicating the test is acceptable.

CONCLUSION

The test substance is considered to be harmful to alga.

TEST FACILITY

Dr U Noack-Laboratorien (2006b)

BIBLIOGRAPHY

- Blok J (1979) A repetitive Die Away (RDA) test combining several biodegradability test procedures. *Int. Biodeterior. Bull.*, **15**, 57-63.
- Dr U Noack-Laboratorien (2006a) C-SAT 050056 Water solubility (Flask Method). (Study No. CWF102991, 3 February 2006) Dr U Noack-Laboratorien, Sarstedt, Germany. (Unpublished report provided by notifier)
- Dr U Noack-Laboratorien (2006b) C-SAT 050056: Alga, growth inhibition test with *Desmodesmus subspicatus*, 72 h. (Study No. SSO102991, 9 January 2006) Dr U Noack-Laboratorien, Sarstedt, Germany (Unpublished report provided by notifier).
- FORS (Federal Office of Road Safety) (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 6th Edition, Canberra, Australian Government Publishing Service.
- Henkel KGaA (1985a) Acute Oral Toxicity Study in Rat (Limit-Test) (Study No. 850341, 19 August 1985) Dusseldorf, Germany, Henkel KGaA (Unpublished report provided by notifier)
- Henkel KGaA (1985b) Acute Dermal Toxicity Study in Rat (Limit-Test) (Study No. 850342, 1985) Dusseldorf, Germany, Henkel KGaA (Unpublished report provided by notifier)
- Henkel KGaA (1985c) Examination of Mutagenicity in Micronucleus test in vivo (Study No. 850389, 20 September 1985) Dusseldorf, Germany, Henkel KGaA (Unpublished report provided by notifier)
- Henkel KGaA (1987) 28 Day Toxicity Study in Rat (Study No. 870031, 1987) Germany, Henkel KGaA (Unpublished report provided by notifier)
- Henkel KGaA (1991) Bewertung der aeroben biologischen Abbaubarkeit in BODIS test. (Report No. 1990/3008, 10 January 1991). Henkel KGaA (Unpublished report provided by notifier).
- Henkel KGaA (1996a) Analytical determination of Sovermol 750 and its metabolites (Study No. 9600981 11, 10 December 1996), Dusseldorf, Germany, Henkel KGaA (Unpublished report provided by notifier).
- Henkel KGaA (1996b) Analysenergebnis: Dynamische Differenzkalorimetrie DSC. (Report No. 96-4327-1, 25 April 1996), Gebäude, Germany, Henkel KGaA, (Unpublished report provided by notifier).
- Henkel KGaA (1996c) Sovermol POL 750: Ultimate biodegradability in the manometric respirometry test (Sapromat System). (Report No. R9600090, 9 February 1996) Düsseldorf, Germany, Henkel KGaA, (Unpublished report provided by notifier).
- Henkel KGaA (1997a) Sovermol 750: Ultimate biodegradability in the manometric respirometry test. (Report No. R9602104, 31 January 1997) Düsseldorf, Germany, Henkel KGaA, (Unpublished report provided by notifier).
- Henkel KGaA (1997b) Sovermol 760: Acute fish toxicity. (Report No. R9700269, 28 July 1997), Dusseldorf, Germany, Henkel KGaA (Unpublished report provided by notifier).
- Henkel KGaA (1999) Sovermol 760 Salmonella/Mammalian-Microsome Mutagenicity Test (Ames Test) (Study No. 9901103 8, 20 August 1999) Dusseldorf, Germany, Henkel KGaA (Unpublished report provided by notifier)
- NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- ToxLabs BioScience GmbH (1998a) Acute Dermal Irritation/Corrosion Test of "SAT 980403" (Study No. 10-3-0111-98, 13 August 1998) Walsrode, Germany, ToxLabs BioScience GmbH (Unpublished report provided by notifier)
- ToxLabs BioScience GmbH (1998b) Acute Eye Irritation/Corrosion Test of "SAT 980403" (Study No. 10-3-0110-98, 13 August 1998) Walsrode, Germany, ToxLabs BioScience GmbH (Unpublished report provided by notifier)

ToxLabs BioScience GmbH (1998c) Skin Sensitisation Test according to Buehler with “SAT 980403” (Study No. 10-5-0109-98, 21 September 1998) Walsrode, Germany, ToxLabs BioScience GmbH (Unpublished report provided by notifier)

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.