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

PUBLIC REPORT

Siloxanes and Silicones, di-Me, Me 3-mercaptopropyl, [(methoxydimethylsilyl)oxy]- and [(trimethylsilyl)oxy]-terminated, telomers with 2-(dimethylamino)ethyl methacrylate, acetates

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

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**Director
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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1946	Wacker Chemie AG	Siloxanes and Silicones, di-Me, Me 3-mercaptopropyl, [(methoxydimethylsilyl)oxy]- and [(trimethylsilyl)oxy]-terminated, telomers with 2-(dimethylamino)ethyl methacrylate, acetates	ND*	≤ 70 tonnes per annum	Component of textile fabric softener

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute Category 2	H401 – Toxic to aquatic life
Chronic Category 2	H411 – Toxic to aquatic life with long lasting effects

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation:
 - Avoid skin and eye contact

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

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

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1,000;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of textile fabric softener, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

(Material) Safety Data Sheet

The (M)SDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

Wacker Chemie AG (ABN: 11 607 113 062)
Unit 1, 35 Dunlop Road
MULGRAVE VIC 3170

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ Da

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume, site of reformulation and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physical and chemical property endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2001)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

WACKER® FC 204 (product containing the notified polymer at $\leq 15\%$ concentration)
JETSOFT® NFS (product containing the notified polymer at $\leq 15\%$ concentration)

CHEMICAL NAME

Siloxanes and Silicones, di-Me, Me 3-mercaptopropyl, [(methoxydimethylsilyl)oxy]- and [(trimethylsilyl)oxy]-terminated, telomers with 2-(dimethylamino)ethyl methacrylate, acetates

CAS NUMBER

340795-93-9

MOLECULAR WEIGHT

$M_n > 1,000$ Da

ANALYTICAL DATA

Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

$> 90\%$

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless to yellowish liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Introduced as an aqueous solution
Boiling Point	Not determined	Expected to decompose without boiling
Density*	1,000 kg/m ³ at 20 °C	(M)SDS
Vapour Pressure	Not determined	Expected to be low based on high molecular weight

Property	Value	Data Source/Justification
Water Solubility	Completely miscible at 20 °C	(M)SDS
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to phase boundaries based on surfactant properties
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on cationic and surfactant properties
Dissociation Constant	Not determined	The notified polymer is a salt and expected to be ionised under environmental conditions
Flash Point	Not determined	Introduced as an aqueous solution
Flammability	Not determined	Introduced as an aqueous solution
Autoignition Temperature	Not determined	Introduced as an aqueous solution
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* Properties of WACKER® FC 204 containing the notified polymer at $\leq 15\%$ concentration in aqueous solution

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer contains reactive end groups that allow the polymer to attach to the textile fabric by chemical reaction. The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification

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

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. It will be imported as a component of formulations (e.g. WACKER® FC 204) at $\leq 15\%$ concentration.

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

Year	1	2	3	4	5
Tonnes	< 50	< 50	< 50	< 70	< 70

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING

The formulations containing the notified polymer at $\leq 15\%$ concentration will be imported in 200 L steel drums and 1,000 L IBCs, and transported by road or rail for distribution. After reformulation, finished textile fabric softener products containing the notified polymer at $\leq 0.8\%$ concentration will be packed in consumer size containers ranging from 500 mL to 5 L, and transported by road or rail to distribution centres and retail outlets.

USE

The imported formulations containing the notified polymer will be used as raw material for formulating commercial or consumer textile fabric softener products. The final concentration of the notified polymer in the finished fabric softeners will be $\leq 0.8\%$. It is anticipated that $> 95\%$ of the finished fabric softener products containing the notified polymer will be used by household consumers and $< 5\%$ of the products will be used by commercial facilities.

OPERATION DESCRIPTION

The imported formulations containing the notified polymer at $\leq 15\%$ concentration will be stored in warehouses and further distributed to reformulation sites for formulation of end-use textile fabric softeners.

Reformulation

The procedures for incorporating imported formulations containing the notified polymer into end-use products may involve both automated and manual handling steps. In general, it is expected that the formulations containing the notified polymer at $\leq 15\%$ concentration will be measured and added to mixing vessels where blending with other ingredients will occur to form finished textile fabric softeners. The blending process is expected to be highly automated and use closed systems with adequate working area ventilation. This process will be typically followed by automated filling of the reformulated finished products into containers of various consumer sizes. During the reformulation process, samples may be taken for quality control purposes.

End use

The finished textile fabric softener products containing the notified polymer at $\leq 0.8\%$ concentration will be used largely by consumers with a small portion of commercial laundry use. Main application of the finished products will involve manually decanting the softeners into washing machine dispensing containers before each washing cycle starts.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage workers	< 0.1	240
Production workers at reformulation sites	7	240
End commercial users	0.1	104

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the notified polymer as a component in imported formulations at $\leq 15\%$ concentration or in finished fabric softeners at $\leq 0.8\%$ concentration, only in the unlikely event of accidental rupture of packaging.

Reformulation

During reformulation, dermal and ocular exposure of workers to the notified polymer at $\leq 15\%$ concentration may occur during transfer to the mixing vessel and quality control processes. Exposure may also occur when workers clean and maintain relevant production equipment. Inhalation of the notified polymer is not expected due to its relatively high molecular weight, unless mists or aerosols of the polymer are formed in working areas. The notifier stated in the submission that the exposure potential is expected to be minimised by the use of engineering controls including good general ventilation and enclosed blending systems, and by the use of personal protective equipment (PPE) such as safety glasses with side protectors, protective clothing and gloves.

End-use

A small portion (< 5%) of the finished textile fabric softener products containing the notified polymer will be used by commercial facilities. Exposure to the notified polymer in the products at $\leq 0.8\%$ concentration may occur in laundry workers where applications of the fabric softeners take place. The principal route of exposure will be dermal, while incidental ocular exposure is also possible. Workers may use some PPE to minimise repeated exposure and good hygiene practices are expected to be in place.

6.1.2. Public Exposure

Finished textile fabric softener products containing the notified polymer will be used by the public. Exposure of the public to the notified polymer at $\leq 0.8\%$ concentration may occur through the use of the finished textile fabric softeners during laundry activities. The principal route of exposure will be dermal, while incidental ocular exposure is also possible. Once used, a small amount of the notified polymer is expected to be bound inextricably to textile fabrics by its reactive end groups. Dermal contact with the bound notified polymer may continually occur when treated clothes are worn.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on a product containing the notified polymer at 15% concentration are summarised in the following table. For full details of the studies, refer to Appendix A.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	mildly irritating
Guinea pig, skin sensitisation – Maximisation test	no evidence of sensitisation

Toxicokinetics, metabolism and distribution

No toxicokinetic information on the notified polymer was provided. Based on the high molecular weight of the notified polymer (> 1,000 Da), low percentage (< 8%) of low molecular weight species (< 1,000 Da), high water solubility and ionic character, the potential for the polymer to cross biological membranes is expected to be limited.

Acute toxicity

An acute oral toxicity study on a product containing the notified polymer at 15% concentration was submitted and showed low toxicity for the test substance. No dermal or inhalation acute toxicity information for the notified polymer was provided.

Irritation and sensitisation

A skin irritation study and an eye irritation study conducted on a product containing the notified polymer at 15% concentration were submitted. At this concentration, the notified polymer was shown to be slightly irritating to the skin and mildly irritating to the eyes. However, the results did not warrant classification for the test substance under the GHS.

When tested at 15% concentration, the notified polymer did not show evidence of skin sensitisation in a guinea pig maximisation test.

Structural alert

The notified polymer contains tertiary ammonium functional groups that are known to be a structural alert for skin corrosion and sensitisation (Barrett et al., 1994; Hulzebos et al., 2005). This is consistent with the skin and eye irritation effects observed for the product containing the notified polymer at 15% concentration.

Health hazard classification

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the available information, the notified polymer at 15% concentration is slightly irritating to skin and mildly irritating to eyes. Systemic effects from the notified polymer are not expected given the limited potential to cross biological membranes.

Workers handling the notified polymer as introduced in imported formulations at $\leq 15\%$ concentration during reformulation may be at risk of slight skin and eye irritation effects. However, significant exposure of these workers to the notified polymer is not expected based on the protective measures in place.

At the proposed low use concentration in the finished textile fabric softener products, no adverse effects are expected from the notified polymer.

Therefore, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Finished textile fabric softener products containing the notified polymer at $\leq 0.8\%$ concentration will be used by the public. At the proposed low use concentration no adverse effects are expected from the notified polymer.

Based on the available information and proposed use scenario, the risk to the public from use of the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported as raw material for reformulation into textile fabric softener formulations. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the product containing the notified polymer is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified polymer from this process to the environment is not expected. Release of the notified polymer during reformulation in Australia is expected to be limited to accidental spills or leaks and residue in import containers. These releases are expected to be collected and disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer is expected to be released to sewer across Australia as a result of its use in laundry products. A small proportion of the notified polymer is expected to be disposed of to landfill as residues in empty end-use containers.

RELEASE OF CHEMICAL FROM DISPOSAL

A small proportion of the notified polymer may remain in end-use containers once the consumer products are used up. Wastes and residues of the notified polymer in empty containers are likely either to share the fate of the container and be disposed of to landfill, or to be released to sewer when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymer. Following its use as textile fabric softeners, the majority of the notified polymer is expected to enter the sewer system, before potential release to surface waters nationwide. The notified polymer is not expected to cross biological membranes and be bioaccumulative, based on its high molecular weight.

The majority of the notified polymer will be released to sewer after use. A proportion of the notified polymer may be applied to land when effluent is used for irrigation, when sewage sludge is used for soil remediation, or disposed of to landfill as collected spills and empty container residue. The notified polymer in water, landfill, soil and sludge are expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon, nitrogen and silicon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated by assuming a worst case scenario, with 100% release of the notified polymer into sewer systems nationwide. Based on its cationic properties and high molecular weight, the PEC has been calculated assuming 90% removal of the notified polymer from influent during sewage treatment plants (STPs) processes through partitioning to sediment or sludge (Boethling and Nabholz, 1997). The resultant PEC in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment

Total Annual Import/Manufactured Volume	70,000	kg/year
Proportion expected to be released to sewer	100 %	
Annual quantity of chemical released to sewer	70,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	191.78	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Removal within STP	90%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	4.24	µg/L
PEC - Ocean:	0.42	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m³). Using these assumptions, irrigation with a concentration of 4.24 µg/L may potentially result in a soil concentration of approximately 28.27 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 141.4 µg/kg and 282.7 µg/kg, respectively.

7.2. Environmental Effects Assessment

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

Endpoint	Result	Assessment Conclusion
Fish Toxicity	96 h LC50 = 8.25 mg/L	Toxic to fish
Daphnia Toxicity	48 h EC50 > 15 mg/L	Inconclusive for the notified polymer

Based on the above ecotoxicological endpoints for the notified polymer, it is expected to be toxic to fish. As the active ingredient of the test substance in the aquatic invertebrates study was only ≤ 15%, the toxic effects of the notified polymer to aquatic invertebrate could not be determined. Therefore, under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009), the notified polymer is formally classified as “Acute Category 2; Toxic to aquatic life”. Based on the acute toxicity and lack of ready biodegradability of the notified polymer, it is formally classified as ‘Chronic Category 2; Toxic to aquatic life with long lasting effects’ under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for fish. An assessment factor of 1,000 was used given only the acute endpoint for fish was available for calculation. The endpoint for aquatic invertebrates was not taken into consideration as the toxicity of the notified polymer was inconclusive.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish, 96 h)	8.25	mg/L
Assessment Factor	1,000	
Mitigation Factor	1.00	
PNEC:	8.25	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC (µg/L)	PNEC (µg/L)	Q
Q - River	4.24	8.25	0.51
Q - Ocean	0.42	8.25	0.051

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Although the notified polymer is not readily biodegradable, it is expected to have a low potential for bioaccumulation based on its high molecular weight.

On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	A product containing the notified polymer at 15%
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar CrI:(WI) BR
Vehicle	None
Remarks - Method	No significant deviations of protocol were noted. The test substance was a water emulsion with the notified polymer at 15% concentration.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose (mg/kg bw)</i>	<i>Mortality</i>
1	3 M	2,000	0/3
2	3 F	2,000	0/3

LD50	> 2,000 mg/kg bw (equivalent to 300 mg/kg bw for the notified polymer)
Signs of Toxicity	No treatment related clinical signs of toxicity were observed.
Effects in Organs	No treatment related abnormalities were found at necropsy. Watery fluid in the uterus found in one of the females was related to a stage in the oestrous cycle.
Remarks - Results	The body weight gain of the test animals was considered by the study authors to be normal.

CONCLUSION	The product containing the notified polymer at 15% concentration is of low toxicity via the oral route.
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TEST FACILITY	NOTOX (1999a)
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A.2. Irritation – skin

TEST SUBSTANCE	A product containing the notified polymer at 15%
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	No significant deviations of protocol were noted. The test substance was a water emulsion with the notified polymer at 15% concentration.

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0.3	0.3	0.3	1	< 48 h	0
<i>Oedema</i>	0	0	0	0	-	0

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

Remarks - Results	Slight erythema was noted for all test animals and resolved within 48 hours.
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CONCLUSION	The product containing the notified polymer at 15% concentration is slightly irritating to the skin.
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TEST FACILITY	NOTOX (1999b)
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A.3. Irritation – eye

TEST SUBSTANCE	A product containing the notified polymer at 15%
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	7 days
Remarks - Method	No significant deviations of protocol were noted. The test substance was a water emulsion with the notified polymer at 15% concentration.

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>Conjunctiva: redness</i>	2.3	2	1.7	3	< 7 d	0
<i>Conjunctiva: chemosis</i>	0.7	0.3	0.3	2	< 72 h	0
<i>Conjunctiva: discharge</i>	1	0.7	0.3	1	< 7 d	0
<i>Corneal opacity</i>	0.3	0	0	1	< 48 h	0
<i>Iridial inflammation</i>	0.3	0	0	1	< 48 h	0

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

Remarks - Results	Application of the test substance resulted in effects on the cornea, iris and conjunctivae. Corneal injury was seen as opacity and epithelial damage (maximum 30 % of the corneal area) in only one animal and completely resolved within 72 hours. Iridial irritation was resolved within 24 hours in two animals and within 48 hours in the remaining animal. Irritation of the conjunctivae was completely resolved within 7 days.
CONCLUSION	The product containing the notified polymer at 15% concentration is mildly irritating to the eye.
TEST FACILITY	NOTOX (1999c)

A.4. Skin sensitisation

TEST SUBSTANCE	A product containing the notified polymer at 15%
METHOD	OECD TG 406 Skin Sensitisation – Maximisation Test
Species/Strain	Guinea pig/Dunkin Hartley, albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: Intradermal 2% Topical 100%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
Vehicle	Water
Positive control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using α -hexylcinnamaldehyde.
INDUCTION PHASE	Induction Concentration: Intradermal 2% Topical 100%
Signs of Irritation	Only very slight erythema was observed in two test animals after intradermal induction. Small scabs were noted in test and control animals after the topical induction which was considered to be related to SDS treatment. No other signs of irritation were noted.
CHALLENGE PHASE	Challenge Concentration: Topical 100%
Remarks - Method	The test substance was a water emulsion with the notified polymer at 15%

concentration. Approximately 24 hours before topical induction, all test sites of the animals were treated with 10% SDS to provoke a mild inflammatory reaction. Only one challenge was applied.

RESULTS

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

Remarks - Results

CONCLUSION

Under the conditions of the test, there was no evidence of reactions indicative of skin sensitisation to the product containing the notified polymer at 15% concentration.

TEST FACILITY

NOTOX (1999d)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Ecotoxicological Investigations

B.1.1. Acute toxicity to fish

TEST SUBSTANCE	JETSOFT (product containing the notified polymer at $\leq 15\%$ concentration)
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static
Species	<i>Oncorhynchus mykiss</i> (Rainbow trout)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg CaCO ₃ /L
Analytical Monitoring	None
Remarks – Method	The test was conducted in accordance with the test guidelines above with no significant deviation from the protocol, and in compliance with GLP standards and principles.

A stock solution of nominal 1 g/L was prepared by dissolving 2 g test item into 2 L test water by intense stirring for 15 minutes. Adequate volumes of this test medium were diluted with test water to obtain desired test concentrations.

RESULTS

Concentration (mg/L) <i>Nominal</i>	Number of Fish	Mortality				
		2 h	24 h	48 h	72 h	96 h
Control	7	0	0	0	0	0
4.6	7	0	0	0	0	0
10	7	0	0	0	0	0
21	7	0	0	0	0	0
46	7	0	0	1	2	2
100	7	0	0	7	7	7

LC50	8.25 mg/L at 96 hours (for the active ingredient)
NOEC	3.15 mg/L at 96 hours (for the active ingredient)
Remarks – Results	All validity criteria for the test were satisfied.

In the test report, the 96 h LC50 and NOEC were reported as 55 mg/L and 21 mg/L respectively, based on nominal concentrations. As the test substance contains 15% of the notified polymer, the 96 h LC50 and NOEC were recalculated to 8.25 mg/L and 3.15 mg/L respectively, to reflect the actual toxic effects caused by the active ingredient.

CONCLUSION	The notified polymer is considered to be toxic to fish.
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TEST FACILITY	IBACON (2000a)
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B.1.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	JETSOFT (product containing the notified polymer at $\leq 15\%$ concentration)
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg CaCO ₃ /L

Analytical Monitoring
Remarks - Method

None

The test was conducted in accordance with the test guidelines above with no significant deviation from the protocol and in compliance with GLP standards and principles.

The test medium of the highest nominal test concentration (100 mg/L) was prepared by dissolving 50 mg test item into 500 mL test water by intense stirring for 15 minutes. Adequate volumes of this test medium were diluted with test water to prepare the test media.

RESULTS

Concentration (mg/L) Nominal	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48 h
Control	20	0	1
4.6	20	0	1
10.0	20	1	1
21.0	20	1	1
46.0	20	0	0
100.0	20	0	0

EC50

> 15 mg/L at 48 hours (for the active ingredient)

NOEC

15 mg/L at 48 hours (for the active ingredient)

Remarks - Results

After 24 hours, one *Daphnia* was immobile at the test concentration of 10 and 21 mg/L. After 48 hours, one *Daphnia* was immobile in the control and in the three lowest test concentrations (4.6 – 21 mg/L). However, this immobilization rate was not estimated as a significant toxic effect as the immobilization rate is also tolerated in the control. Furthermore, no immobilization and no other signs of intoxication were observed at the higher test concentrations of 46 and 100 mg/L.

In the test report, the 48 h EC50 and NOEC were reported as > 100 mg/L and 100 mg/L respectively, based on nominal concentrations. As the test substance contains 15% of the notified polymer, the 96 h LC50 and NOEC were recalculated to > 15 mg/L and 15 mg/L respectively, to reflect the actual effects caused by the active ingredient. Since the notified polymer was not tested above 15 mg/L, the toxicity to aquatic invertebrates could not be determined.

CONCLUSION

As a specific toxicity endpoint for the notified polymer was not determined in this study, the toxicity of the polymer to aquatic invertebrates was inconclusive.

TEST FACILITY

IBACON (2000b)

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