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

FULL PUBLIC REPORT

**CGX UVA 006 in Makrolon DP1-1816 MAS 073 / Makrolon DP1-1852 MAS 074 /
Makrolon DP1-1858 MAS 073**

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
NICNAS**

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FULL PUBLIC REPORT**CGX UVA 006 in Makrolon DP1-1816 MAS 073 / Makrolon DP1-1852 MAS 074 /
Makrolon DP1-1858 MAS 073****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Ciba Specialty Chemicals Pty Ltd (ABN: 97 005 061 469)
235 Settlement Road
Thomastown VIC 3074

and

Bayer Material Science (Division of Bayer Australia Ltd, ABN: 22 000 138 714)
500 Wellington Road
Mulgrave VIC 3170

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; Spectral data; Purity; Identity and % weight of impurities; Additives/adjuvants; Import volume; Identity of customer sites, % notified chemical in imported and final products.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Europe, United States, Canada, Japan, Korea

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

CGX UVA 006
CG 36-1600
TKA 40256

MARKETING NAME(S)

Makrolon DP1-1816 MAS 073
Makrolon DP1-1852 MAS 074
Makrolon DP1-1858 MAS 073

ANALYTICAL DATA

Reference NMR, IR, HPLC, GC and mass spectra were provided. Results of elemental analysis were also provided.

3. COMPOSITION

DEGREE OF PURITY
>95%

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa

Slightly yellow powder

Property	Value	Data Source/Justification
Melting Point	73.7±0.5°C (average onset temperature)	Measured
Boiling Point	>320°C	Measured
Density	1139 kg/m ³ at 20°C	Measured
Vapour Pressure	~ 5.4 x 10 ⁻²⁵ kPa at 25°C	Calculated
Water Solubility	<0.7274 mg/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	
Partition Coefficient (n-octanol/water)	log Pow = 10.8 at 20°C	Calculated
Surface Tension	73.8 mN/m at 20°C	Measured
Adsorption/Desorption	log K _{oc} = 8.73 at 20°C	Measured
Dissociation Constant	Not determined	
Particle Size	Inhalable fraction (<100 µm): 100% Respirable fraction (<10 µm): 32.24% MMAD = 16.5µm	Measured
Flash Point	>200°C	Measured
Flammability	Not flammable	Measured
Autoignition Temperature	Not auto-ignitable	Measured
Explosive Properties	Not predicted to be explosive	Predicted
Oxidizing Properties	Non-oxidising	Predicted

Discussion of Observed Effects

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

Reactivity

Based on the structure of the notified chemical, it is likely to be incompatible with strong acids, strong bases and strong oxidising agents. There are no known conditions that are likely to cause instability – the product is stable at room temperature. The notified chemical decomposes at approx. 320°C. Expected hazardous decomposition products are oxides of carbon (carbon monoxide, carbon dioxide) and oxides of nitrogen (NO_x).

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).

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported at concentrations of <10% as granules.

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

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

PORT OF ENTRY

Sydney, Melbourne, Brisbane

IDENTITY OF MANUFACTURER/RECIPIENTS

Ciba Specialty Chemicals Pty Ltd
235 Settlement Road
Thomastown VIC 3074

Bayer Material Science
(Division of Bayer Australia Ltd)
500 Wellington Road
Mulgrave VIC 3170

TRANSPORTATION AND PACKAGING

The notified chemical will be imported by sea in robust 25-kg plastic bags, 650 and 950 kg octabin bags. These products will be transported by road to the notifier's warehouses prior to dispatching to the customer sites, mainly by road. The formulated product will be packaged into 15, 20, 25 kg plastic bags for transport to Bayer in different countries and to other customers.

USE

Ultraviolet light absorber for plastics, e.g. polycarbonate, for use in a diverse range of plastic products, such as signage and roofing applications. The notified chemical will not be used in food packaging products.

OPERATION DESCRIPTION

Reformulation

Products containing the notified chemical will be transported as required from the storage area to the production area by forklift. The notified chemical in the granules (<10% notified chemical) will be weighed manually before being added to a blending vessel for mixing with other components. The resulting mixture is transferred by automated means to the feed hopper of an extruder from which molten strands are chopped into pellets and allowed to cool before being discharged via a closed transfer system for packaging by manual means. Pellets containing <10% of the notified chemical will then be delivered to customer sites.

Moulding

At the customers' factories, the pellets containing the notified chemical are either weighed or added to the feed hopper by manually cutting open the bags or by manually scooping or pouring into the hopper. The notified chemical within the pellets (and possibly other additives) are mixed with polymer in a typical ratio of around 1 : 10, reformulated pellets : polymer in the hopper. The resulting mixture is again melted and extruded under pressure through dies or moulds of the appropriate shapes to produce the final plastic article (<10% notified chemical). The moulded plastic article can be moved manually or using an automated production line.

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>
Reformulation	15	16	1/month
Moulding line operator / maintenance	5	16	1/month

Exposure Details

The notified chemical will be encapsulated within the granules of the products in which it is imported. As such, exposure is likely to be negligible during all handling of the product that occurs within Australia. Minimal exposure may occur via the following routes:

Transport and storage

During transport, warehousing, and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached. In addition, workers wear protective equipment (overalls/ industrial clothing), and the product will be handled in the warehouse by forklift

handling of pallets. Thus worker exposure to the notified chemical is expected to be negligible.

Reformulation

The main routes of worker exposure to the notified chemical (<10% of imported product) are dermal and accidental ocular exposure during weighing and adding the imported granules to the automated batching and pellet extruding machine. Exposure to dust should be minimised by the fact that the loading equipment is used under a dust extractor, and blending occurs in a closed extruder. Personal protective equipment will also be worn, including coveralls, dust masks, gloves and eye protection when carrying out the above activities.

Moulding

The most likely route of worker exposure to the notified chemical is dermal contact and this may occur when opening bags and manually charging the polymer containing the notified chemical into an injection moulding machine. Exposure would be mitigated by the enclosed and automated nature of the injection moulding machines and the local exhaust ventilation fitted in process areas to capture fugitive emissions from the heated resin. In addition, workers wear protective equipment including gloves, safety glasses and overalls when handling pellets containing the notified chemical. Handling of finished articles would not result in worker exposure to the notified chemical, as it will be encapsulated in the polymer matrix and not available for exposure.

6.1.2. Public exposure

The notified chemical will be present in a variety of end use consumer products. In such products the encapsulation of the notified polymer within the polymer matrix renders it non-bioavailable. Therefore, public exposure to the notified polymer during use of such products is expected to be negligible.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	low toxicity, oral LD50 >2000 mg/kg bw
Rat, acute dermal toxicity	low toxicity, LD50 >2000 mg/kg bw
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL = 200 mg/kg bw/day NOAEL = 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity –in vitro mammalian chromosome aberration test	non genotoxic

The notified chemical was found to be slightly irritating to the eyes. The NOEL in a 28-day oral repeat dose study in rats was 200 mg/kg bw/day on the basis of changes in locomotor activity. The NOAEL was established as 1000 mg/kg bw/day in this study.

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

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Acute toxic potential

Dermal and accidental ocular are the main routes of worker exposure to the notified chemical, particularly during manual handling of granules or pellets containing the notified chemical at concentrations of <10%. Skin or eye irritation is unlikely to occur during such exposure, given that the notified chemical is non-irritating to the skin, slightly irritating to the eyes, and is present at concentrations below the irritation cut off (ie. <20%). If dermal exposure occurs, absorption through the skin is not expected to be significant, given its relatively high molecular

weight (>500), low water solubility (<1 mg/mL), and high partition coefficient (log P >6) (European Commission 2003). Acute effects from exposure to the notified chemical are unlikely to occur, given its low acute toxicity (oral and dermal). In addition, in granular or pellet form, the notified chemical is expected to be encapsulated within the granules or pellets, and as such, exposure should be negligible.

Repeat dose toxic potential

During manual handling of the granules or pellets of the notified chemical, the risk of adverse effects resulting from repeated exposure to the notified chemical are unlikely to be significant considering the NOAEL is 1000 mg/kg bw/day. In particular, encapsulation of the notified chemical within granules or pellets is likely to limit direct contact with the notified chemical.

The risk of effects from inhalation exposure to the notified chemical will be limited by encapsulation of the notified chemical within granules as imported, or in pellets following reformulation. The notifier has provided information indicating that the imported form of the notified chemical will contain only negligible inhalable or respirable fractions. As such, worker exposure to dust/powder of the notified chemical is likely to be below the general exposure standard for dusts of 10 mg/m³ (NOHSC 1995). However, if the notified chemical were to be imported in powder form the risk of inhalation effects could not be excluded, given that approximately 32% of the notified chemical is of respirable size.

The risk to workers from use of the notified chemical is expected to be low, given its encapsulation within granules and pellets, the various control measures in place during reformulation and moulding operations, and the low hazard of the chemical.

6.3.2. Public health

The risk to the public from exposure to the notified chemical is expected to be negligible, given its non-hazardous nature and the fact that it will be encapsulated within a matrix and not be bioavailable upon contact with consumer products in which it is contained.

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 as a component of MAKROLON DP1-1816 MAS073 or MAKROLON DP1-1852 MAS074 and will be used for the production of moulded or extruded plastic articles such as sheets for roofing and signage. There will be no environmental exposure associated with the manufacture of the notified chemical in Australia.

Small quantities of the chemical could be lost during preliminary mixing with polymer and other components prior to extrusion of the plastic articles, and all of this is likely to be placed into landfill. Small spills of chemical would be swept up and either returned to the mix or disposed with other factory waste to landfill. It is expected the mixing and extrusion operations would be performed using local exhaust extraction/filtrations so that any particulate matter released to the air during operations would be captured and retained on the filters and all solid material retained on the filters would also be placed into landfill.

On occasion, the extrusion equipment would be cleaned out and some solid scrap material removed from the equipment and also placed into landfill, as would any of the granulated product lost during packaging. Emptied bags of the chemical would be shaken into the feed hopper to remove residual material and then be placed into landfill.

Apart from spills, no release of the chemical during dry mixing of the extrusion compound with polymer, filler and other materials is expected during injection moulding of the final articles although it is possible that some scrap plastic may be produced during finishing of the final products. All such waste would be placed into landfill.

While no details of likely release of the notified chemical are available, large releases are not expected. If it is assumed that 2% is lost during extrusion / moulding preparation and a further 3% lost as scrap and waste from injection moulding, then total losses associated with manufacturing activities are 5%.

RELEASE OF CHEMICAL FROM USE

Once incorporated into plastic/polymer articles the notified chemical will be immobilised in the polymer matrix and little release is expected.

RELEASE OF CHEMICAL FROM DISPOSAL

Disposal via incineration in the presence of air is the disposal route of choice. This will produce simple oxides of carbon and nitrogen along with water. Spilled or reject material during manufacture of moulded or extruded articles will be collected and reused. Regranulated product unsuitable for reuse is bagged and disposed to secure landfill as normal industrial waste via a waste contractor. Packaging should be emptied as far as possible, and disposed to licensed waste landfill site. In landfill, the notified chemical is expected to be immobile, and remain associated with soil and sediment. Eventually, the notified chemical is expected to degrade via biotic and abiotic processes to form simple organic and nitrogen based compounds.

7.1.2 Environmental fate

A ready biodegradability test was conducted on the notified chemical, and it was determined that it cannot be classed as ready biodegradable. A bioaccumulation test was also conducted and it was found that the notified chemical is slightly bioaccumulating. For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

As the notified chemical is not expected to be released to the aquatic environment under the proposed use pattern, a Predicted Environmental Concentration is not able to be sensibly derived.

7.2. Environmental effects assessment

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

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	LC50 >100 mg/L (WAF*)	Not toxic effect up to the limit of its solubility.
Daphnia Toxicity	EC50 >100 mg/L (WAF*)	Not harmful up to the limit of its solubility.
Algal Toxicity	EC50 >100 mg/L (WAF*)	Not harmful up to the limit of its solubility.
Inhibition of Bacterial Respiration	IC50 >100 mg/L (WAF*)	Not harmful up to the limit of its solubility.

*Water Accommodated Fraction

The notified chemical had no acute effect on various trophic levels tested up to its solubility limit under the strict test conditions. For the details of the environmental effect studies please refer to Appendix C.

7.2.1 Predicted No-Effect Concentration

Based on the results of the ecotoxicological testing the Predicted No-Effect Concentration has been calculated as follows:

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
EC50	>100 mg/L

Assessment Factor	100
PNEC:	>1000 µg/L

7.3. Environmental risk assessment

Without a PEC, it is not possible to derive a Risk Quotient. The only environmental release expected throughout the life cycle of the notified chemical under the proposed use pattern is through disposal to landfill. In landfill, the notified chemical is expected to be immobile, and overtime degrade to simple organic and nitrogen based compounds. Should the notified chemical be disposed of by incineration, it is expected to be thermally decomposed to form various oxides of carbon and nitrogen and water. While the notified chemical was found to be slightly bioconcentrating, this is not expected to pose a risk to the environment as release to the aquatic environment is not expected. Therefore, the notified chemical is not expected to pose an unacceptable risk to the aquatic environment.

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 *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

8.2. Human health risk assessment

8.2.1. Occupational health and safety

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

8.2.2. Public health

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

8.3. Environmental risk assessment

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

9. MATERIAL SAFETY DATA SHEET

The MSDS of products containing the notified chemical 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 was found to be in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003).

10. RECOMMENDATIONS

REGULATORY CONTROLS AICS Annotation

- When the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS) the entry should be annotated with the following statement:
 - Only to be used for non-cosmetic applications.

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:

- Avoid eye contact.
- Wear dust mask.
- 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.

Environment

Disposal

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

Emergency procedures

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

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 use in plastics, or is likely to change significantly;
 - the form of the imported chemical has changed from granules to powder;
 - the amount of chemical being introduced has increased from 10 tonnes per annum, 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** 73.7 ± 0.5°C (average onset temperature)

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.

Remarks Differential scanning calorimetry

TEST FACILITY RCC (2002)

Boiling Point >320°C at 101.3kPa

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.

Remarks Differential scanning calorimetry.
The notified chemical did not boil at temperatures below 320°C, at which decomposition commenced.
The boiling point of the notified chemical was estimated to be approximately 703°C using Meissner's method (Lyman et al. 1990).

TEST FACILITY RCC (2002)

Density 1139 kg/m³ at 20°C

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.

Remarks Gas comparison pycnometer

TEST FACILITY RCC (2002)

Vapour Pressure ~ 5.4 x 10⁻²⁵ kPa at 25°C

METHOD OECD TG 104 Vapour Pressure (Estimation Method).
EC Directive 92/69/EEC A.4 Vapour Pressure (Estimation Method).
Modified Watson Correlation (Lyman et al. 1990).

Remarks The vapour pressure was calculated based on the estimate of the boiling point (above).

TEST FACILITY RCC (2002)

Water Solubility < 0.7274 mg/L at 20°C

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.

Remarks Column Elution Method. 6.01 g of glass beads were weighed and transferred into a 100 mL round bottom flask. 2.09 g of test item was added and dissolved in about 15 mL tetrahydrofuran. After ultrasonification for about 3 minutes, the tetrahydrofuran was blown off with a stream of nitrogen. The dry loaded carrier was poured into the elution column, which was then filled with water. The system was equilibrated for approximately 2 hours. The water solubility was determined to be below the limit of determination of 0.7247 mg/L using the column elution method.

TEST FACILITY RCC Ltd (2002e)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

<i>pH</i>	<i>T (°C)</i>	<i>t</i> _½ <hours or days>
4	20°	not soluble
7	20°	not soluble
9	20°	not soluble

Remarks It was not possible to increase the solubility of the notified substance with the use of a solubilizer (THF). Peaks obtained, if any, were too small to allow quantification or even to follow a degradation curve. Due to the very low solubility, no further testing could be performed with the notified substance.

TEST FACILITY RCC Ltd (2002f)

Partition Coefficient (n-octanol/water) $\log P_{ow}$ at 20°C = 10.8 (estimated)

METHOD OECD 107 Partition Coefficient (n-octanol/water): Shake Flask Method
OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks Neither the HPLC method nor the flask-shaking method were applicable, thus, the $\log P_{ow}$ was estimated by a model calculation using KOWWIN ver 1.6.

TEST FACILITY RCC Ltd (2002g)

Surface Tension 73.8 mN/m at 20°C

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.

Remarks Concentration: 90% of saturation concentration. Based on criteria outlined in the OECD Guideline, the notified substance is not a surface-active substance.

TEST FACILITY RCC Ltd (2002n)

Adsorption/Desorption $\log K_{oc}$ = 8.73 at 20°C.

METHOD OECD 121 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography
EC Directive 2001/59/EC C.19 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography

Remarks The test item eluted after the last reference substance, 2,4-DDT. Therefore, the $\log K_{oc}$ was extrapolated from the regression curve. This indicates that the notified substance is very immobile and its preference is to remain in soil.

TEST FACILITY RCC Ltd (2002h)

Dissociation Constant Not determined.

METHOD OECD TG 112 Dissociation Constants in Water

Remarks The notified substance is not dissociated or protonated in the environmentally relevant pH range (5 to 8). However, the notified chemical does contain functionality, which will be dissociated in the basic range of pH. At a pH value of 9.4, 50% of the notified substance molecules are dissociated.

TEST FACILITY RCC Ltd (2002i)

Particle Size

METHOD "Particle size distribution, fibre length and diameter distribution" European Commission guidance document.
Laser diffraction method.

Range (μm)	Mass (%)
< 1.0	1.67
< 5.0	15.78
< 10.0	32.24
< 20.0	58.08
< 30.0	75.06
< 40.0	85.52
< 50.0	91.79
< 60.0	95.60
< 70.0	97.81

	< 80.0	99.16
	< 90.0	99.84
	< 100	100.00
Remarks	Mass median diameter: 16.5±0.6µm 100% inhalable; 32.24% respirable Dispersing agent: ethanol with a drop of Sympatens SHO/400	
TEST FACILITY	The notifier has provided information to show that only a negligible fraction of the pellets in which the notified chemical is imported are likely to be of inhalable or respirable size. RCC (2003)	
Flash Point	>200°C	
METHOD	EC Directive 92/69/EEC A.9 Flash Point.	
Remarks	Determined using the Pensky-Martens method (closed cup). A flash point was not observed at temperatures below which decomposition commenced.	
TEST FACILITY	RCC (2002)	
Flammability	Not flammable	
METHOD	EC Directive 92/69/EEC A.10 Flammability (Solids).	
Remarks	The notified chemical could not be ignited with a flame during a contact time of approximately 2 minutes. The notified chemical melted immediately on contact with the ignition source.	
TEST FACILITY	RCC (2002)	
Autoignition Temperature	Not auto-ignitable	
METHOD	EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.	
Remarks	The substance does not auto-ignite at temperatures up to 400°C, and decomposed during the experiment.	
TEST FACILITY	RCC (2002)	
Explosive Properties	Not predicted to be explosive.	
METHOD	Similar to EC Directive 92/69/EEC A.14 Explosive Properties.	
Remarks	The molecular structure, estimated oxygen balance, and decomposition energy did not indicate that the notified chemical would possess explosive properties. The exothermic decomposition energy was determined using DSC, and was found to be ~290J/g. The onset point of the exothermic peak was at ~320°C with a maximum at 440°C.	
TEST FACILITY	RCC (2002)	
Oxidizing Properties	Predicted to be non-oxidising	
Remarks	Based on the structure of the notified chemical (UN Recommendations on the Transport of Dangerous Goods – Orange Book, 3 rd Edition, 1999) it is not predicted to be oxidising.	
TEST FACILITY	RCC (2002)	

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/HanBrl: Wist (SPF)
Vehicle	Polyethylene glycol (PEG 300)
Remarks - Method	No significant protocol deviations.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	3 F	2000	0
II	3 M	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	No clinical signs were evident during the course of study.
Effects in Organs	No macroscopic findings were observed at necropsy.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
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TEST FACILITY	RCC Ltd (2002p)
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B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/HanBrl: WIST (SPF)
Vehicle	Polyethylene glycol (PEG 300)
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5 M	2000	0
II	5 F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No local signs of toxicity were observed during the study period.
Signs of Toxicity - Systemic	No systemic signs of toxicity were observed during the study period.
Effects in Organs	No macroscopic findings were observed at necropsy

CONCLUSION	The notified chemical is of low toxicity via the dermal route.
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TEST FACILITY	RCC Ltd (2002q)
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B.3. Irritation – skin

TEST SUBSTANCE Notified chemical

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 1 male, 2 females
Vehicle Purified water
Observation Period 72 hours
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations.

RESULTS

Remarks - Results The notified chemical did not elicit any skin reactions at the application site of any animal at any of the observation times.

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

TEST FACILITY RCC Ltd (2002r)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical

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 1 male, 2 females
Observation Period 72 hours
Remarks - Method No significant protocol deviations.

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>Conjunctiva: redness</i>	0.33	0	0.67	2	<72hr	0
<i>Conjunctiva: chemosis</i>	0	0	0	1	<24hr	0
<i>Conjunctiva: discharge</i>						
<i>Corneal opacity</i>	0	0	0	0	0	0
<i>Iridial inflammation</i>	0	0	0	0	0	0

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

Remarks - Results Slight to moderate reddening of the conjunctivae was observed in all animals 1 hour after treatment and slight reddening continued to be observed in one animal up to the 24 hour reading and in another animal up to the 48 hour reading.
Slight swelling of the conjunctivae was apparent in two animals 1 hour after treatment.
Slight to moderate reddening of the sclerae was noted in all animals 1 hour after treatment and persisted in one animal up to the 24 hour reading.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY RCC Ltd (2002s)

B.5. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – Guinea pig maximisation test, Magnusson and Kligman.
EC Directive 96/54/EC B.6 Skin Sensitisation - Guinea pig maximisation test, Magnusson and Kligman.

Species/Strain Guinea pig/Ibm: GOHI; SPF (Himalayan spotted)

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 10% in polyethylene glycol 300 (PEG 300)

MAIN STUDY

Number of Animals Test Group: 10 Control Group: 5

INDUCTION PHASE

1st induction Induction Concentration:
intradermal: 10% in polyethylene glycol 300 (PEG 300)

2nd induction Induction Concentration:
epidermal: 25% in polyethylene glycol 300 (PEG 300)

Signs of Irritation Some irritation was observed at the 24 and 48 hour observations.

CHALLENGE PHASE

1st challenge epidermal: 1% in polyethylene glycol 300 (PEG 300)

Remarks - Method No significant protocol deviations.

RESULTS

Remarks - Results One animal of the test group was found dead on test day 15, that is, after epidermal induction. No macroscopic findings were noted at necropsy, and the cause of death was not established, and thus it was considered to be unrelated to treatment.
None of the control and test animals showed skin reactions after the challenge treatment with the notified chemical.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY RCC Ltd (2002t)

B.6. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain Rat/HanBrl:WIST (SPF)

Route of Administration Oral – gavage.

Exposure Information Total exposure days: 28 days;
Dose regimen: 7 days per week;
Post-exposure observation period: 14 days

Vehicle Polyethylene glycol (PEG 300)

Remarks - Method No significant protocol deviations. Dosage levels were chosen based on a previous dose range-finding study.

RESULTS

<i>Dose mg/kg bw/day</i>	<i>Number and Sex of Animals</i>	<i>Mortality</i>
0	5 M, 5 F	0
50	5 M, 5 F	0
200	5 M, 5 F	0
1000	5 M, 5 F	0
0 (recovery)	5 M, 5 F	0
1000 (recovery)	5 M, 5 F	0

Mortality and Time to Death

No mortality was observed during the treatment or recovery phases.

Clinical Observations

There were isolated incidences of clinical observations in some of the animals, such as soft or pale faeces, localised alopecia, and scabbing. However, these observations were not considered to be related to the test material, either due to the effects being considered the result of the vehicle, a passive effect of the test material, or due to the absence of similar effects at higher dose levels.

No findings of toxicological relevance were noted during the functional observational battery evaluations at any dose levels. Statistically significant increases and decreases in mean limb grip strength values were observed in males and females, respectively, that had been treated with 200 mg/kg/day. Similar changes were not observed in animals treated with higher doses of the test material, and hence the changes were considered to be incidental.

Slight but statistically significant reductions in mean locomotor activity were noted during the first measurement interval (0-15 minutes) in both sexes treated with 1000 mg/kg/day. Such differences contributed to slightly lower total locomotor activity in both sexes and was considered to be related to the test article, although only a minor effect.

No significant changes were observed in body weight or food consumption.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology

There were a number of statistically significant changes in haematological parameters in both sexes throughout the treatment period, mainly in animals treated with 1000 mg/kg/day. Such changes were not considered to be toxicologically relevant, largely due to the fact that the values were within historical control values.

Clinical Biochemistry

A number of statistically significant differences were noted in several clinical biochemistry parameters in both sexes compared to the controls. Such changes were considered to be incidental, as most of the levels were within the range of historical control data.

Urinalysis

Some changes were observed in urinary output, specific gravity, and osmolality in both sexes. The changes were not considered to be related to test substance administration, either due to incidental variations in the control values, or the fact that the values were within the historical control values.

Effects in Organs

No test item related differences in the absolute or relative organ weights were noted at any dose level after four weeks treatment. After two weeks recovery, there were some changes in organ weights, however, in the absence of correlating microscopical changes the differences were considered to be unrelated to treatment.

There were no significant macroscopic or microscopic findings in any of the organs tested.

Remarks – Results

The only treatment related finding was a transient minor reduction of locomotor activity in both sexes treated with 1000 mg/kg/day. This was not considered to be a significant effect.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 200 mg/kg bw/day in this study, based on changes in locomotor activity. The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg/day, as the locomotor activity changes were not considered to be significant effects.

TEST FACILITY RCC Ltd (2002u)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation and Pre incubation procedure
Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA
Metabolic Activation System Liver fraction (S9 mix) from rats pretreated with phenobarbital/ β -naphthoflavone
Concentration Range in Main Test a) Plate incorporation test (with and without metabolic activation):
33-5000 μ g/plate
b) Pre incubation test (with and without metabolic activation):
10-5000 μ g/plate
Vehicle DMSO
Remarks - Method No significant protocol deviations.
The positive control used for the assay performed without metabolic activation with WP2uvrA was methyl methane sulfonate, which is not recommended by the test method.

RESULTS

Remarks - Results No visible reduction of the background growth was observed up to the highest concentration tested. Toxic effects were observed at higher concentrations in strain TA1535 without S9 mix and in strains TA1537 and TA 98 with and without S9 mix. In the second test, toxic effects were observed at the two highest concentrations in strain TA1535 without S9 mix.

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

TEST FACILITY RCC Ltd (2002v)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Species/Strain Chinese hamster
Cell Type/Cell Line V79
Metabolic Activation System Liver fraction (S9 mix) from rats pretreated with phenobarbital/ β -naphthoflavone
Vehicle Tetrahydrofuran
Remarks - Method No significant protocol deviations.

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Absent</i>			
Test 1	1.6, 3.1*, 6.3*, 12.5*, 25.0, 50.0	4hr	18hr
Test 2	1.6, 3.1*, 6.3*, 12.5*, 25.0, 50.0	18hr	18hr
Test 3	1.6, 3.1, 6.3*, 12.5*	28hr	28hr
<i>Present</i>			
Test 1	6.3, 12.5*, 25.0*, 50.0*, 100.0, 200.0	4hr	18hr
Test 2	6.3, 12.5*, 25.0*, 50.0*, 100.0, 200.0	4hr	28hr

*Cultures selected for metaphase analysis.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>		
	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>			
Test 1	>50.0	≥6.3	Negative
Test 2	>50.0	≥12.5	Negative
Test 3	>12.5	≥12.5	Negative
<i>Present</i>			
Test 1	>200.0	≥25.0	Negative
Test 2	>200.0	≥25.0	Negative

Remarks - Results

The aberration rates of the cells after treatment with the notified chemical (exclusive gaps) were close to the range of the solvent control values and within the range of historical control data. Two single statistically significant increases were observed in Test 1 in the presence of activation and in Test 2 in the absence of activation after treatment with 12.5µg/mL. Whilst these increases were statistically significant compared to the low responses of the solvent control data, they were within the range of historical control data. As such, they were not considered to be biologically relevant.

CONCLUSION

The notified chemical was not clastogenic to V79 Chinese hamster cells treated in vitro under the conditions of the test.

TEST FACILITY

RCC Ltd (2002w)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified substance.
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test. EC Directive 92/69/EEC C.4-C Biodegradation: Determination of the "Ready" Biodegradability: Carbon Dioxide Evolution Test
Inoculum	Aerobic activated sludge from wastewater treatment plant.
Exposure Period	28 days
Auxiliary Solvent	Nil
Analytical Monitoring	IC analysis
Remarks - Method	No significant protocol deviations.

RESULTS

<i>Notified substance</i>		<i>Sodium Benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
5	-2.1	5	61.2
9	-2.1	9	68.7
12	-2.7	12	73.8
14	-2.6	14	76.7
19	-1.5	19	79.9
28	-2.8	28	80.4

Remarks - Results The notified substance was found to be not biodegradable under the test conditions within 28 days.

CONCLUSION The notified chemical cannot be classed as ready biodegradable.

TEST FACILITY RCC Ltd (2002x)

C.1.2. Bioaccumulation

TEST SUBSTANCE	Notified substance
METHOD	OECD TG 305 Bioconcentration: Flow-through Fish Test. EC Directive 98/73/EC C.13 Bioconcentration: Flow-Through Fish Test.
Species	<i>Cyprinus carpio</i>
Exposure Period	Exposure: 28 days Exposure: 28 days
Auxiliary Solvent	
Concentration Range	0.02 and 0.2 mg/L
Analytical Monitoring	HPLC
Remarks - Method	No significant protocol deviations

RESULTS

Bioconcentration Factor < 9

CT50

Remarks - Results The bioconcentration factor of the notified substance in common carp (*Cyprinus carpio*) during the exposure were 1 - 5 times and less than the detectable limit (9 times) at the high exposure level (0.2 mg/L) and the low exposure level (0.02 mg/L) respectively.

CONCLUSION The notified chemical is slightly bioconcentrating.

TEST FACILITY Institute of Ecotoxicology Co., Ltd (2002)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified substance

METHOD OECD TG 203 Fish, Acute Toxicity Test – Static Test/96-hours.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish- Static Test/96-hours.

Species Zebra Fish (*Brachydanio rerio*)

Exposure Period 96 hours

Auxiliary Solvent None

Water Hardness 250 mg CaCO₃/L

Analytical Monitoring HPLC with UV/VIS detection

Remarks – Method Due to the low water solubility of the test item, a supersaturated dispersion of the test item with a loading rate of 100 mg/L was continuously stirred at room temperature in the dark for 24 hours. This dispersion was filtered and the undiluted filtrate containing a maximum concentration of dissolved test item was used as the test medium.

The analytically measured test item concentrations at the start and end of the test in the analysed test medium samples were below the limit of quantification (LOQ) of 0.001 mg/L test item. Therefore, the biological results are related to the loading rate of the test item.

No significant protocol deviations were reported.

RESULTS

Concentration mg/L		Number of Fish	Mortality				
Nominal	Actual		1 h	24 h	48 h	72 h	96 h
Control		7	0	0	0	0	0
100		7	0	0	0	0	0

LC50 >100 mg/L (WAF) at 24 hours.
>100 mg/L (WAF) at 48 hours.
>100 mg/L (WAF) at 72 hours.
>100 mg/L (WAF) at 96 hours.

NOEC (or LOEC) 100 mg/L (WAF) at 96 hours.

Remarks – Results The notified substance had no acute effect on zebra fish up to its solubility limit under the test conditions.

CONCLUSION The notified chemical had no toxic effect to zebra fish (*Brachydanio rerio*) up to its limit of solubility.

TEST FACILITY RCC Ltd (2002y)

C.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified substance

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – 48-Hour Immobilisation Test
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – 48-Hour Immobilisation Test

Species *Daphnia magna*

Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg CaCO ₃ /L
Analytical Monitoring	HPLC
Remarks - Method	Due to the low water solubility of the test item, a supersaturated dispersion of the test item with a loading rate of 100 mg/L was continuously stirred at room temperature in the dark for 24 hours. This dispersion was filtered and the undiluted filtrate containing a maximum concentration of dissolved test item was used as the test medium.

The analytically measured test item concentrations at the start and end of the test in the analysed test medium samples were below the limit of quantification (LOQ) of 1.3 µg/L test item. Therefore, the biological results are related to the loading rate of the test item.

No significant protocol deviations were reported.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control		20	0	0
100		20	0	0

LC50	>100 mg/L at 24 hours >100 mg/L at 48 hours
NOEC (or LOEC)	100 mg/L at 48 hours
Remarks - Results	The notified substance had no acute toxic effects on <i>Daphnia magna</i> up to the water solubility limit. No remarkable observations were made concerning the appearance of the test medium. The test medium was a clear solution throughout the whole test duration.

CONCLUSION	The notified chemical had no toxic effect to <i>Daphnia magna</i> up to the limit of its solubility.
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TEST FACILITY	RCC Ltd (2002z)
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C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified substance.
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METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
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Species	<i>Scenedesmus subspicatus</i>
Exposure Period	72 hours
Concentration Range	100 mg/L
Auxiliary Solvent	None
Water Hardness	24 mg CaCO ₃ /L
Analytical Monitoring	HPLC with UV/VIS-detection.
Remarks - Method	Due to the low water solubility of the test item, a supersaturated dispersion of the test item with a loading rate of 100 mg/L was continuously stirred at room temperature in the dark for 24 hours. This dispersion was filtered and the undiluted filtrate containing a maximum concentration of dissolved test item was used as the test medium.

The analytically measured test item concentrations at the start and end of the test in the analysed test medium samples were below the limit of quantification (LOQ) of 0.001 mg/L test item. Therefore, the biological results are related to the loading rate of the test item.

No significant protocol deviations were reported.

RESULTS

	<i>Biomass</i>		<i>Growth</i>	
	<i>E_bC₅₀</i> mg/L at 72 h	<i>NOEC</i> mg/L	<i>E_rC₅₀</i> mg/L at 72 h	<i>NOEC</i> mg/L
	>100 (WAF)	100 (WAF)	>100 (WAF)	100 (WAF)
Remarks - Results	The 72-hour LOEC (lowest concentration tested with toxic effects) and the 72-hour EC ₅₀ for the mean algal biomass and the mean growth rate were clearly higher than the loading rate of 100 mg/L.			
CONCLUSION	The notified substance had no toxic effect on the algae up to its solubility limit in test water.			
TEST FACILITY	RCC Ltd (2002aa)			

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified substance
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.
Inoculum	Aerobic activated sludge from wastewater treatment plant
Exposure Period	3 hours
Concentration Range	6.25, 12.5, 25, 50 and 100 mg/L
Remarks – Method	In addition, two controls and three different concentrations of the reference item 3,5-dichlorophenol (5, 16 and 50 mg/L) were tested in parallel.
	No significant protocol deviations were reported
RESULTS	
IC ₅₀	>100 mg/L (WAF)
NOEC	100 mg/L (WAF)
Remarks – Results	The 3-hour NOEC to activated sludge microorganisms was at least at the limit of water solubility of the notified substance under the present test conditions or at least nominal 100 mg/L. The results of the control and toxicity control confirmed the suitability of the activated sludge and the method used
CONCLUSION	The notified substance had no toxic effect on the activated sludge microorganisms up to its solubility limit in test water.
TEST FACILITY	RCC Ltd (2002ab)

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