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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in KX-6049

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ecolab Pty Limited (ABN: 59 000 449 990)
6 Hudson Avenue
Castle Hill, NSW 2154

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Spectral Data, Methods of Detection and Determination, Degree of Purity

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Dissociation Constant, Particle Size, Acute Inhalation Toxicity, Repeated Dose Toxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Japan Inventory of Existing & New Chemical Substances (ENCS), Number: (2)-630
USA Toxic Substances Control Act (TSCA), EPA Accession Number is 156071

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
KX-6049 (contains the notified chemical)

SPECTRAL DATA

METHODS	FT-IR Spectroscopy and NMR Spectroscopy
TEST FACILITY	Henkel KGaA (2001e)

METHODS OF DETECTION AND DETERMINATION

METHOD	Reversed phase liquid chromatography
TEST FACILITY	Ecolab (1991)

3. COMPOSITION

DEGREE OF PURITY
>90% (for the test chemical). The notified chemical is formed *in situ*, in solution.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is not commercially available. It is formed *in situ* in aqueous solution, and the product containing it (<1% in KX-6049) will be manufactured in Australia by the notifier.

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

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

USE
Sanitiser for non-food contact surfaces and food contact surfaces. The product containing the notified chemical will predominantly be used as an acid liquid sanitiser for cleaning equipment in dairy plants, breweries, wineries, beverage and food processing plants.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

TRANSPORTATION AND PACKAGING
KX-6049, containing the notified chemical at <1%, will be supplied in 20 kg and 200 kg pack sizes in high-density polyethylene (HDPE) cubes (25 L) or drums (205 L). It may also be supplied in 1000 L intermediate bulk containers (IBCs). All containers will have a vented closure to prevent pressure build-up inside the container. The properties of the notified chemical necessitate its storage in safe locations, away from sunlight, below 38ºC, and with appropriate segregation from other materials.

All containers are packed and transported on timber pallets by road to the customer's site. As the product is Class 5.1(8) Dangerous Goods, it must be transported in accordance with the current Australian Dangerous Goods (ADG) Code (6th Edition).

5.2. Operation description

Manufacture and packaging:

The notified chemical is manufactured in-situ in aqueous solution, via an acid catalysed equilibrium reaction at ambient temperature, within the product KX-6049. The latter is formulated in a closed blending vessel that is pre-cleaned to ensure there is no residual organic material present in the vessel as this could cause significant decrease in the product's stability. The raw materials are blended together and gravity fed from the mix tank into HDPE 25 L cubes and 205 L drums. After packaging the product is left for 7 days until chemical equilibrium is reached. At this point, the product KX-6049 containing <1% of the notified chemical is sampled for quality control (QC) analysis before despatch to customers.

Use as an acid liquid sanitiser:

The product KX-6049 is used as an acid liquid sanitiser on equipment in dairies, breweries, wineries and in beverage and food processing plants, where it is diluted before use. Users are instructed to dilute KX-6049 (containing <1% notified chemical) with water at 0.13-0.26% v/v (1.3-2.6 mL KX-6049 per L of water) at ambient temperature. This results in a final use concentration of notified chemical of <0.0026%). These solutions should be prepared fresh daily. The dilution and method of handling will depend on the type and size of the surface to be sanitised.

Food contact surfaces will be cleaned of gross food particles, washed with a detergent solution, and then rinsed with potable water. The surface will be then exposed to the KX-6049 solution in a manner that is appropriate for the equipment (eg circulated, sprayed or rinsed onto surfaces). Exposure to the sanitising solution should be for a period of not less than one minute, after which the solution will be removed or drained away. The surfaces will not be rinsed after treatment. Sanitising solutions will not be re-used for sanitising after use, but may be used for general purposes such as cleaning.

Sanitising solutions containing the notified chemical will be applied in different ways dependent on the application. Typical uses are sanitising food contact surfaces, as a final sanitising bottle rinse and for continuous treatment of conveyors for raw food. Articles that are sanitised include pipelines,

vats, tanks, fillers, evaporators, pasteurisers and aseptic equipment.

- Continuous treatment of conveyors for meat and poultry or fruit and vegetables occurs during food processing. Controlled volumes of sanitising solutions containing 0.26% v/v are applied to the return portion of conveyors through nozzles that are placed so as to maximise drainage and prevent puddle formation.
- Sanitising of peelers, collators, slicers and saws will be carried out when the conveyors are free of food products, using a coarse spray of 0.26% v/v KX-6049. This is carried out during production breaks.
- KX-6049 may also be used as a final sanitising rinse for returnable and non-returnable bottles (eg glass or PET) at a 0.13% v/v concentration.
- If used in pipes, it will be flushed through the system at the recommended dilution.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Manufacturing Operator	2	2	100
Process Operator	2	2	100
Quality Control	1	1	100
Warehouse	2	1	100
Transport and Storage	2	4	200
End User	100	0.5	200

Exposure Details

Manufacturing Operators and Process Operator/Packaging:

The same manufacturing operators perform both of these roles. Exposure to the notified chemical is not expected, except in the case of accidental spills or breaching of containers. Negligible exposure to the notified chemical is anticipated during the manufacturing process, as equilibrium has not yet been reached and its concentration is very low. All the ingredients of the product KX-6049 are carefully delivered at ambient temperature through dedicated lines into the mixing vessel, a closed system.

As the notified chemical is formed from hazardous chemicals, the operator supervising the product is required at all times to wear personal protective clothing, including eye goggles, impervious gloves, proper footwear and apparel. Operators receive in-house training to understand the importance of personal protective clothing and the consequences to health if not used. Material Safety Data Sheets (MSDS) are also readily accessible for the raw materials.

Quality Control:

After the 7-day post-manufacturing period, the product is sent for QC analysis. Any exposure is likely to be due to accidental splashing or spills, which could result in dermal or ocular exposure to a concentration of the notified chemical of <1%. Inhalation exposure is expected to be low as the notified chemical has a low vapour pressure. As the product KX-6049 containing the notified chemical at < 1% is itself corrosive and hazardous, precautions against exposure are taken during sampling and analysis. As part of Good Laboratory Practice procedures, the chemist must at all times wear proper eye goggles, impervious gloves, proper footwear, and lab coat to prevent any exposure to the chemical. Quality control analysis will take place 24 times in a year and takes approximately 1 hour.

Warehouse/Transport and Storage:

The properties of the notified chemical necessitate its storage in safe locations, away from sunlight, below 38ºC, and with appropriate segregation from other materials. When in the warehouse, the product containing the notified chemical is stored in containers and there is little risk of exposure. The warehouse personnel supervising the transport and storage of the notified chemical are required to wear protective clothing including gloves, apron and face shield or goggles at all times. If there is any exposure to the product from a spill, an adequate supply of water is available at all times for general first aid purposes, as part of an eyewash and safety shower facility.

End use as an acid liquid sanitiser:

Varied exposure to the product containing the notified chemical may occur, depending on the type

and scale of the equipment to be cleaned. During dilution, workers may have dermal and/or ocular to KX-6049 containing < 1% of the notified chemical, or to much lower concentrations. During cleaning processes, dermal or ocular exposure to concentrations of < 0.003% may occur, and inhalation exposure may occur if aerosols are generated eg through spray application of the cleaning solution. Based on the low vapour pressure and the low concentration of notified chemical, inhalation exposure during inhalation or end-use should not occur in the absence of aerosols. As the product containing the notified chemical is corrosive, the label and MSDS inform the end user is of the risks associated with exposure to the product and the appropriate protective equipment that should be worn. Recommended measures to prevent exposure during use include appropriate protective clothing, gloves, and eye/face protection.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Limited environmental release is anticipated during the production of the notified chemical in KX-6049, since the manufacture of the notified chemical involves mixing of ingredients in a closed system at ambient temperature. The notified chemical decomposes in water and is not actually expected to enter the environment after wastewater treatment. Wastewater effluent is flushed to an onsite wastewater pit where the water will be treated prior to disposal to sewer.

Any ingredients remaining on the mixer vessel walls, product pipelines or package filter units will be rinsed to a wastewater drain. It is difficult to predict actual release figures during these operations. However, from the data collected in the USA for the production of KX-6049, it has been estimated that, from a production run of 2000 gallons (7571 L, per run), 2 gallons (7.57 L; which contains <0.08 kg of the notified chemical) of the ingredients in the formulation of KX-6049 are released.

Due to the lack of significant volatility, none of the components used in the manufacture of KX-6049, including the notified chemical, are likely to be discharged to air.

RELEASE OF CHEMICAL FROM USE

Insignificant environmental releases of the notified chemical in KX-6049 are expected by the notifier during use, due to its degradability, distributed use pattern and dilution. Under worst case conditions:

- A food or beverage plant will use up to 250 gallons (946 L) per day of sanitiser solution containing the notified chemical at up to 0.26% v/v (or 2.6 mL/L), which is the highest allowable use concentration according to the product label attached. Therefore, the highest allowable use rate is equivalent to 8.79 g/day.
- This is discharged by industry to a wastewater storage reservoir with “millions of litres of water.”
- Therefore, the amount of the notified ingredient, as a daily loading concentration to the wastewater facility or sewer, is estimated as 0.12 ppb. This will be further reduced as a result of wastewater treatment process (typically by at least 90% since all of the effluent materials are degradable in wastewater treatment).

However, given the release scenarios outlined in Section 5.2 above, it will be assumed as a worst case that the entire manufacture volume (up to 10 tonnes per annum) may enter the sewer.

5.5. Disposal

After use, empty drums will be flushed with water prior to being sent to the drum recycler. If they are IBCs, they are returned to the manufacturer of the notified chemical. Therefore, there is unlikely to be much residual product in the containers. The smaller end use containers, if not recycled, would most likely be disposed of to landfill.

The majority of the manufacture volume of the notified chemical will be disposed of through the sewage system as a result of its proposed use pattern.

5.6. Public exposure

The product KX-6049 containing the notified chemical is not available to the general public, therefore no public exposure during manufacture or use is expected. If accidental spillage occurred during transport of KX-6049, it is possible that the public could be exposed to the notified chemical.

The notified chemical is a component of an acid liquid sanitiser for use on food contact surfaces, such

as in dairy plants, food processing plants and breweries. Therefore, the public could be potentially exposed to very low concentrations of the notified chemical through contact with food produced in these plants. However, dietary exposure to the notified chemical is unlikely as a result of its use, as it rapidly degrades when diluted for use on food contact surfaces.

Indirect public exposure as a result of the release the notified chemical to the environment is expected to be negligible. After wastewater treatment, environmental concentrations of the notified chemical are expected to be insignificant, as it decomposes rapidly in water.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa White waxy solid

Melting Point 31ºC

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature. US EPA OPPTS 830.7200 Melting Point/Melting Range.
Remarks	Capillary method using an electronic controlled heating system.
TEST FACILITY	IBACON (2002b)

Boiling Point 114ºC at 100.8 kPa

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature. US EPA OPPTS 830.7220 Boiling Point.
Remarks	Capillary method using an electronic controlled heating system. The colour of the notified chemical changed from white to yellow to red at about 160ºC using a heating rate of 1 $K.min^{-1}$.
TEST FACILITY	IBACON (2002a)

Density 1.098 g/cm^3 at 20 ± 1ºC

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Density was determined using a gas comparison pycnometer.
TEST FACILITY	IBACON (2002c)

Vapour Pressure 1.4 x 10^{-4} kPa at 20ºC

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure. US EPA OPPTS 830.7950 Vapor Pressure.
Remarks	The test item was dried by heating (at 20°C for 1 h). The vapour pressure was determined at 5°C increments from -5°C to 20°C using a vapour pressure balance. A value for the vapour pressure at 20ºC was determined by extrapolation from the graph of the logarithm of the vapour pressure as a linear function of the inverse of the thermodynamic temperature.
TEST FACILITY	Infracor (2002)

Water Solubility 1.5 ± 0.03 g/L in distilled water at 20 ± 0.1ºC
1.0 ± 0.03 g/L in pH 5 buffer at 20 ± 0.1ºC
0.5 ± 0.07 g/L in pH 7 buffer at 20 ± 0.1ºC

METHOD	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method Test material (100 mg) was weighed into screw capped glass bottles and 20 mL tri-distilled water, pH 5 citrate, or pH 7 phosphate buffer were added. Test solutions thermostated at 20 ± 0.1°C for 1 day. The experiments were conducted in triplicate for each pH value. The concentration of the test material in the solutions was determined using HPLC.
TEST FACILITY	PTRL Europe (2002a)

Surface Tension 26.6 mN/m at 20 ± 1°C

METHOD	OECD TG 115 Surface Tension of Aqueous Solutions. EC Directive 92/69/EEC A.5 Surface Tension.
Remarks	Test was performed using a ring tensiometer on a 90% saturated solution of the

notified chemical. Based on this test result, the notified chemical can be considered to be surface active.

TEST FACILITY IBACON (2002d)

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.

pH	*T (°C)*	*$t_{½}$ (days)*
4.0	50	0.8
	25	8
7.0 (1st phase)	50	0.07
	25	1.2
7.0 (2nd phase)	50	0.15
	25	2
9.0	50	0.015
	25	0.2

Remarks Reversed phase HPLC with UV detection at 210 nm was used for determination in the buffer systems. Rates at 2°C were extrapolated from data from higher temperatures using Arrhenius' equation.

The notified chemical undergoes moderate to very fast hydrolysis under the conditions of the test. At pH 7.0, the hydrolysis of the notified chemical displayed non-pseudo-first order kinetics, with a 1st phase at higher concentrations of notified chemical, and a 2nd phase at lower concentrations. This was speculated in the report to be a result of auto-hydrolytic activity at higher concentrations.

This indicates that the notified chemical is likely to hydrolyse in the aquatic environment and rapidly in alkaline solutions.

TEST FACILITY PTRL Europe (2002b)

Partition Coefficient (n-octanol/water) log P_{ow} = 1.87 at 20°C (calculated)

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Computer simulation employing the Rekker Method using the KOWWIN v1.66 developed by the US EPA.
TEST FACILITY Covance Laboratories (2002)

Adsorption/Desorption Not determined

Remarks Due to the strong oxidising properties and surface active nature of the notified chemical, an adsorption-desorption test is technically not feasible. Upon contact, the notified chemical reacts very rapidly with any oxidisable substances, including soil organic matter. In the course of oxidising reactions, the notified chemical itself is to a major proportion reduced. In addition, the notified chemical undergoes hydrolysis in the presence of water. Therefore, the notified chemical is not expected to be part of adsorption/desorption processes.

TEST FACILITY SCC (2003a)

Dissociation Constant Not determined

Remarks The notified chemical contains a functional group which is able to undergo dissociation and would be expected to display typical dissociation behaviour. However, the rapid hydrolysis of the chemical would make the measurement of the dissociation constant difficult.

Particle Size Not applicable

Remarks The notified chemical is only present in solution.

Flash Point 88ºC at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks No significant protocol deviations.
It was noted that cellulose cloths soaked in the notified chemical were liable to spontaneous combustion at 24ºC. It also undergoes a strong exothermic degradation beginning at 50ºC.
TEST FACILITY Henkle KGaA (2001a)

Flammability (Contact with water) No gas was released.

METHOD EC Directive 92/69/EEC A.12 Flammability (Contact with Water).
Remarks The notified chemical cannot be classified as flammable according to the above method.
TEST FACILITY Henkel KGaA (2001b)

Oxidizing Properties Has oxidising properties

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks From the structural formula of the notified chemical, it can be concluded that it has oxidising properties.
TEST FACILITY SCC (2002)

Pyrophoric properties Pyrophoric upon contact with air at room temperature.

METHOD EC Directive 92/69/EEC A.13 Pyrophoric Properties of Solids and Liquids.
Remarks Test was performed with both a liquid and a solid sample of the notified chemical. The solid did not ignite after six tests, but the liquid ignited immediately upon pouring into a porcelain bowl.
TEST FACILITY Henkel KGaA (2001c)

Autoignition Temperature Spontaneous ignition at room temperature (as above)

METHOD EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks Substances, which show spontaneous ignition in contact with air at ambient temperature, should not be submitted to this test according to method 92/69/EEC A-16. The notified chemical is considered to be pyrophoric according to the test method EC Directive A.13 (above). Therefore, the determination of the relative self-ignition temperature is not required for the notified chemical.
TEST FACILITY SCC (2003b)

Explosive Properties The notified chemical is not sensitive to shock or friction.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The mechanical sensitivity tests for shock and friction did not yield positive results.
TEST FACILITY Henkel KGaA (2001d)

Reactivity

Remarks The notified chemical has oxidizing properties. It is not reactive with water, apart from being rapidly hydrolysed in solution. The pure, isolated notified chemical is able to spontaneously combust in air at ambient temperatures. However, the notified chemical only occurs in aqueous solution, and therefore will not be a hazard as a result of this property.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	Low toxicity, LD50 >2000 mg/kg bw
Rat, acute dermal	Not determined
Skin irritation (in vitro)	Corrosive
Eye irritation (in vitro)	Corrosive
Guinea pig, skin sensitisation – adjuvant test	No evidence of sensitisation
Rat, repeat dose	Not determined
Genotoxicity – bacterial reverse mutation	Mutagenic
Genotoxicity – *in vitro* chromosome aberration test	Clastogenic
Genotoxicity – *in vitro* mammalian cell gene mutation test (HRPT-LOCUS)	Not mutagenic
Genotoxicity – *in vivo* micronucleus assay	Not mutagenic
Genotoxicity – *in vivo* unscheduled DNA synthesis	Not genotoxic
Toxicokinetic analysis	Bioavailability after dermal contact is not expected. Bioaccumulation or formation of toxic intermediates after oral uptake is not expected.

7.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical 99%.

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.
US EPA OPPTS 870.1100 Acute Oral Toxicity.

Species/Strain: Rat/HsdBrl:WH Wistar
Vehicle: 1% aqueous carboxymethylcellulose (10ml/kg bw/animal)
Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	200 mg/kg bw	0/6
2	3/sex	2000 mg/kg bw	0/6

LD50: >2000 mg/kg bw
Signs of Toxicity: No effects on body weight were seen. One male animal displayed a slight reduction in spontaneous activity 24 hours after administration of 200 mg/kg bw notified chemical, but this had cleared by 48 hours.
Effects in Organs: No gross pathological changes were observed at necropsy.
Remarks - Results: None

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

TEST FACILITY: BSL Bioservice (2002a)

7.2. Acute toxicity – dermal

Based on the structural moieties of the notified chemical and toxicological data for similar compounds, it can be predicted that the notified chemical is corrosive. The expected corrosive potential to the skin was demonstrated in an *in vitro* skin corrosion assay (Section 7.4, below). In addition, the notified chemical is not expected to be systemically available after dermal application, due to its reactivity. It is therefore concluded that for animal welfare reasons, no dermal test is warranted.

TEST FACILITY: SCC (2003c)

7.3. Acute toxicity – inhalation

The pure notified chemical has a low vapour pressure of 1.4 x 10^{-4} kPa at 20ºC. The notified chemical is present as a <1% solution in KX-6049. At the recommended use concentration, the notified chemical will be further diluted to <0.0026%. Significant inhalation exposure is not expected given the use pattern of the product.

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical 99%.
METHOD	OECD TG 431 In Vitro Skin Corrosion: Human Skin Model Test. EC Directive 2000/33/ EC B.40 Skin Corrosion.
Species/Strain	Reconstituted three-dimensional human skin model EpiDerm™
Vehicle	None, however the test item was moistened with 25 µL of water, in order to ensure good contact with the skin.
Observation Period	3 and 60 minutes
Remarks - Method	Since corrosive chemicals are cytotoxic after a short time exposure to the stratum corneum of the epidermis, the cytotoxic effects of the test item on EpiDerm™, a reconstituted three dimensional human epidermis model, was determined. The test item was applied topically and compared with positive and negative controls. Cytotoxicity is expressed as the reduction of mitochondrial dehydrogenase activity measured by formazan production from MTT after exposure periods of 3 minutes and 60 minutes and compared to those of the concurrent negative controls.
RESULTS	The relative mean relative tissue viability after 3 minutes treatment was decreased below 50%. By 60 minutes treatment, the tissues were destroyed – mean relative tissue viability was ~5%.
Remarks	Under the given conditions the test item showed corrosive effects. The controls, positive (8 N KOH) and negative (distilled water) performed as expected, validating the assay.
CONCLUSION	The notified chemical is corrosive to the skin.
TEST FACILITY	BSL Bioservice (2003a)

7.5. Irritation – eye

TEST SUBSTANCE: Notified chemical 99%.

METHOD: CAM Assay (no OECD or EEC guideline available)

Species/Strain: The study was performed using the chorioallantoic membrane (CAM) of incubated hens' eggs.

Number of Animals: 6 eggs

Observation Period: 5 minutes

Remarks - Method: The notified chemical was placed directly onto the chorioallantoic membrane. Changes were observed as a model of the potential for a chemical to damage mucous membranes. The time taken for each reaction to occur was recorded and an irritation score (IS) was calculated according to the following formula:

IS = ([(301-secH)/300] x 5 x S) + ([(301-secL)/300] x 7 x S) + ([(301-secC)/300] x 9 x S)

Where:

Sec = time (seconds) of first occurrence of reaction
H = Haemorrhage
L = Vascular Lysis
C = Coagulation
S = 0.1 if H, C, L is grade 1 (weak reaction)
0.5 if H, C, L is grade 2 (moderate reaction)
1 if H, C, L is grade 3 (strong reaction)

The mean score was calculated from irritation scores for each egg for each test group. The result is then evaluated according to the following table:

Mean Irritation Score	*Evaluation*
0-1.9	Not irritant
2.0-5.9	Slight irritant
6.0-10.9	Moderate irritant
11.0-21.0	Severe irritant

RESULTS

Egg	Haemorrhage (sec)	S	Lysis (sec)	S	Coagulation (sec)	S	IS	Mean IS
1	60	1	80	1	100	1	15.20	
2	55	1	75	1	100	1	15.40	
3	60	1	85	1	95	1	15.24	
4	25	1	35	1	60	1	18.04	
5	45	1	60	1	70	1	16.82	
6	58	1	75	1	95	1	15.50	
								16.03

Remarks - Results: The positive controls (0.1 N NaOH and 1% sodium dodecyl sulfate) gave scores within the expected ranges.
According to the evaluation criteria of the test, the notified chemical is classified as a severe irritant.

CONCLUSION: The notified chemical is a severe irritant to the eye.

TEST FACILITY: BSL Bioservice (2003b)

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical 99%
METHOD	OECD TG 406 Skin Sensitisation – Guinea Pig Maximisation Assay. EC Directive 96/54/EC B.6 Skin Sensitisation – Guinea Pig Maximisation Assay. US EPA OPPTS 870.2600 Skin Sensitisation.
Species/Strain	Guinea pig/Hsd Poc:DH
PRELIMINARY STUDY	Maximum Non-irritating Concentration: Intradermal: 5% notified chemical in cotton seed oil Topical: 10% notified chemical in vaseline
MAIN STUDY	
Number of Animals	Test Group: 10 F Control Group: 5 F
INDUCTION PHASE	Induction Concentration: intradermal: 5% notified chemical in cotton seed oil (± Freund's complete advuvant) topical: 10% notified chemical in Vaseline (after treatment of skin with sodium lauryl sulfate)
Signs of Irritation	No skin reactions were observed throughout the study.
CHALLENGE PHASE	
1st challenge	topical: 5% notified chemical in cotton seed oil
Remarks - Method	No significant protocol deviations. Concentrations of 5%, 10%, 25% and 50% in vaseline were applied topically in the preliminary test.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*	
		24 h	*48 h*
Test Group			
10 F	5% notified chemical	0/10	0/10
Control Group			
5 F	0% (vehicle)	0/5	0/5

Remarks - Results	Animals of the test group showed normal weight gain as compared to historical data and the animals of the control group. In the preliminary test, topical application at 5% showed no signs of irritation after 48 h, and at 10% slight irritation was noted at 48 h. Slight to severe irritation was observed for the 25% and 50% concentrations at 4 h, 24 h and 48 h.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	BSL Bioservice (2002b)

7.7. Repeat dose toxicity

The notified chemical, formed *in situ* in KX-6049, was not tested in isolation for repeated dose toxicity in humans or animals because of its corrosive nature.

The notified chemical is predicted to be corrosive, demonstrated in an *in vitro* skin corrosion assay. Due to its reactivity the notified chemical is not expected to be systemically available after dermal application. As corrosive chemicals are cytotoxic after a short exposure to the stratum corneum of the epidermis, it was concluded that due to animal welfare reasons no repeated dermal toxicity test could be performed to test repeated exposure.

Repeated exposure of operators and end users to the notified chemical is not expected during normal use, as KX-6049 is a hazardous product. Personal protective equipment such as using proper eye goggles, impervious gloves, proper foot wear and apparel is required for handling the concentrated product to prevent any repeated exposure to the notified chemical.

A 28-day oral repeated dose study via drinking water on another peroxide compound yielded a LOAEL of 0.13 mg/kg bw/day, based on observed haematological changes.

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical 99%.
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. US EPA OPPTS 870.5100 Bacterial Reverse Mutation Assay.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	Phenobarbital/β-naphthoflavone-induced S9 liver microsomes
Concentration Range in Main Test	a) With metabolic activation: 0-10 µg/plate b) Without metabolic activation: 0-10 µg/plate
Vehicle	DMSO solvent
Remarks - Method	Plate incorporation procedure. No significant protocol deviations. Due to toxic effect of ethanol in the pre-incubation test, the experiment was performed as a plate incorporation test. Due to the wide range of toxicity in the different tester strains, the following concentrations of the test item were prepared and used: Experiment I: 0.316, 1.0, 3.16, 10.0, 31.6, 100, 316.2, 1000 and 2500 µg/plate. Experiment II: (TA 1535, TA 1537 and TA 102) 1.0, 2.5, 5.0, 10, 25, 50, 100, 250, 500 and 1000 µg/plate. (TA 98 and TA 100) 0.78, 1.56, 3.125, 6.25, 12.5, 25, 50, 100, 250, 500 and 1000 µg/plate.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Experiment I	≥ 100	≥ 10.0 (TA 1537, TA 102)	>2500	Positive
Experiment II	-	≥ 10.0 (TA 1535, TA 1537)	>2500	Positive
Present				
Experiment I	≥ 1000	≥ 100 (TA 1537)	>2500	Negative
Experiment II	-	≥ 250 (TA 1537, TA 98)	>2500	Negative

Remarks - Results	Toxic effects of the test item (indicated by a reduction of the background lawn or by a reduction of the spontaneous rate) were observed in all tester strains used. The toxic effect was more pronounced without S9 mixture (without metabolic activation). The increase in the revertant colony numbers in tester strain TA 102 slightly exceeded the trigger value of 2-fold increase specified in the test protocol compared to concurrent control (Experiment I: 2.2-fold increase at 31.6 µg/mL; Experiment II: 2.4-fold increase at 25 µg/mL) in both experiments, without metabolic activation. Some indications for a dose-dependency of the induction of revertant colonies were noted in addition. With metabolic activation no increase of revertant colony numbers was observed. In all other tester strains no increase in revertant colony numbers was detected in the presence or absence of metabolic activation. As positive controls, reference mutagens were tested in parallel to the test item. They showed a distinct increase in induced revertant colonies.
CONCLUSION	The notified chemical was mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BSL Bioservice (2002d)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical 99%
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test. US EPA OPPTS 870.5375 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	V79 cells
Metabolic Activation System	Phenobarbital/β-naphthoflavone-induced S9 liver microsomes
Vehicle	Ethanol
Remarks - Method	No significant protocol variations were reported. A pre-experiment for toxicity was not performed. An additional test (Experiment III) was carried out with the same conditions as Experiment I, but a closer spacing of concentrations, in order to recheck the clastogenic effect found in in the absence of metabolic activation in Experiment I.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (hours)*	*Harvest Time (hours)*
Absent			
Experiment I	25*, 50, 100*, 200, 400*	4	20
Experiment II	25*, 50, 100*, 200, 400*, 800, 1600	20	20
Experiment III	200*, 300*, 400*	4	20
Present			
Experiment I	50, 100*, 250, 500*, 1000, 1600*	4	20
Experiment II	25, 50*, 100, 200*, 400, 800*	4	20

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Experiment I	-	400	> 400	Positive
Experiment II	-	400	> 400	Negative
Experiment III	-	200	> 400	Positive
Present	-			
Experiment I	-	> 1600	> 1600	Negative
Experiment II	-	> 800	> 800	Negative

Remarks - Results

A reduction in the mitotic index was observed with and without metabolic activation in all experiments.

The test item induced structural chromosome aberrations after treatment with the notified chemical, when tested without metabolic activation with a 4 h incubation period. The effects did not occur in the presence of metabolic activation.

An increase in the incidence of polyploid cells seen in Experiment I without metabolic activation was not evident when the test was repeated in Experiment III.

Genotoxic effects seen without metabolic activation in Experiment I were predominantly chromatid breaks and chromatid-type exchanges, and those seen in Experiment III were mainly gaps and chromatid breaks. The lack of genotoxic effects in Experiment II may be due to the different culture conditions (longer incubation time). The different results may be a result of the high reactivity of the notified chemical.

Positive controls yielded the appropriate genotoxic effects in all experiments, indicating that the experiments were performing correctly.

CONCLUSION

The notified chemical was clastogenic to V79 Chinese hamster cells treated *in vitro* under the conditions of the test.

TEST FACILITY

BSL Bioservice (2002c)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical 99%.
METHOD	OECD TG 476 In vitro Mammalian Cell Gene Mutation Test. EC Directive 2000/32/EC B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test. US EPA OPPTS 870.5300 In vitro Mammalian Cell Gene Mutation Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	V79 cells
Metabolic Activation System	Phenobarbital/β-naphthoflavone-induced S9 liver microsomes
Vehicle	Ethanol
Remarks - Method	No significant protocol deviations. The study was performed using identical procedures each with and without metabolic activation. The notified chemical was initially tested at a range of concentrations to determine the cytotoxicity of the notified chemical. Cytotoxicity was determined in the basis of cell viability counting, after staining with the XTT dye method. On this basis, 1200 µg/mL was selected as the maximum dose for the main test. In the main test, 3-4 days after exposure to the notified chemical, cell cultures were subcultured in normal medium. Then, at 6-7 days following exposure, the cells were subcultured into selection medium. In this medium, mutant cells are selected by exposure to 6-thioguanine, which kills any normal cells. The mutant cells were then allowed to grow for another 8-9 days, when mutant colonies were counted.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Selection Time*
Absent			
Cytotoxicity test	4.1, 13.5, 45, 150, 500, 1600	4 h	-
Main test	10, 25, 50, 75, 100, 200, 400, 800, 1200	4 h	8-9 d
Present			
Cytotoxicity test	4.1, 13.5, 45, 150, 500, 1600	4 h	-
Main test	10, 25, 50, 100, 500, 750, 1000, 1200	4 h	8-9 d

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Cytotoxicity test	45-150		> 1600	-
Main test		800	> 1200	Negative
Present				
Cytotoxicity test	150-500		> 1600	-
Main test		750-1000	> 1200	Negative

Remarks - Results	The positive controls, tested in parallel with the notified chemical, produced the expected response, validating the performance of the assay. The highest mutation factor of 1.59 was observed at 800 µg/mL without metabolic activation. This was within historical controls. This assay is only effective at assaying mutations in the HRPT locus, and the selection method only selects mutants in the HRPT gene. If the notified chemical induced other mutations, this test would not detect them.
CONCLUSION	The notified chemical was not mutagenic to the HRPT locus of V79 cells treated *in vitro* under the conditions of the test.

TEST FACILITY BSL Bioservice (2003c)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE Notified chemical 99%

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity Mammalian Erythrocyte Micronucleus Test.
US EPA OPPTS 870.5395 Mammalian Erythrocyte Micronucleus Test.

Species/Strain Mouse/NMRI

Route of Administration Oral – gavage

Vehicle 1% aqueous carboxymethylcellulose

Remarks - Method This study was performed to investigate the potential of the test substance to induce micronuclei in polychromatic erythrocytes (PCE) in the bone marrow of the mouse. The test item was formulated in 1% of CMC, which was also used as vehicle control. The volume administered orally was 20 mL/kg bw, except the positive control group, which was treated with 10 mL/kg bw.

The bone marrow cells were collected for micronuclei analysis 24 hours and 48 hours after a single administration of the notified chemical. At least 2000 polychromatic erythrocytes (PCEs) per animal were scored for micronuclei. To describe a cytotoxic effect due to the treatment with the test item the ratio between polychromatic and total erythrocytes was determined in the same sample and reported as the number of PCEs per 2000 erythrocytes.

The highest dose administered (1500 mg/kg bw) was based on results obtained in a pre-experiment on toxicity.

Analysis of the formulations was carried out to confirm their stability up to 30 minutes. The results suggested that some degradation may have occurred, especially in the low dose solutions, potentially leading to lower doses than planned being received by the animals.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5/sex	0	24
II (low dose)	5/sex	375	24
III (mid dose)	5/sex	750	24
IV (high dose)	5/sex	1500	24
V (high dose)	5/sex	1500	48
VI (positive control, CP)	5/sex	40	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity All doses of the notified chemical in the main study induced some toxic signs, such as reduction of spontaneous activity and ruffled fur. More severe toxic symptoms appeared with increasing dose. Some of these resolved after 24 hours (eg eyelid closure and abdominal position). Two females and one male died after treatment with the highest dose. However, 5 animals per sex and dose were able to be evaluated for the occurrence of micronuclei.
However there was no change in the mean number of polychromatic erythrocytes (PCEs) after treatment with the test item, compared to the mean value of PCEs in the vehicle control.

Genotoxic Effects In comparison to the corresponding vehicle and historical controls, there was no biologically relevant or statistically significant enhancement in the frequency of the detected micronuclei with any dose level used at any time point after administration of the test item.

Remarks - Results Although clinical signs indicated some toxicity, the notified chemical did

not exert any cytotoxic effects in the bone marrow and therefore it cannot be demonstrated that the test substance reached the bone marrow. The positive control showed a substantial increase of induced micronucleus frequency. A statistically significant increase in micronuclei was noted in the high dose 24 h group, however this was within historical controls, and was attributed to the low mean micronucleus rate of the vehicle control group in this assay.

CONCLUSION The notified chemical was not mutagenic under the conditions of this *in vivo* micronucleus assay.

TEST FACILITY RCC-CCR (2004a)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE Notified chemical 99%

METHOD OECD TG 486 Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells in vivo.
EC Directive 2000/32/EC B.39 Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells in vivo.

Species/Strain	Rat/Wistar HanIbm: WIST (SPF)
Route of Administration	Oral – gavage
Vehicle	1% aqueous carboxymethylcellulose
Remarks - Method	No deviations from the protocol occurred that would affect the test's validity.

Male rats were used for the main test, as no sex-related differences were noted in a preliminary toxicity test.

The test animals were treated with a single dose of the notified chemical (or positive control), and then sacrificed after either 2 or 16 hours. Primary hepatocyte cultures were established, exposed to methyl-^{3}H-thymidine, which is incorporated if DNA repair (UDS) occurs. The incorporation is measured by autoradiography.

Analysis to determine stability of the solutions indicated the test item was stable during the treatment phase (approximately 30 minutes), however higher dilutions seem to be less stable.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
Ia (vehicle control)	4 M	0	2
Ib (vehicle control)	4 M	0	16
IIa (low dose)	4 M	625	2
IIb (low dose)	4 M	625	16
IIIa (high dose)	4 M	1250	2
IIIb (high dose)	4 M	1250	16
IVa (positive control, DMH)	4 M	40	2
IVb (positive control, 2-AAF)	4 M	100	16

DMH = N,N'-dimethylhydrazinedihydrochloride; 2-AAF = 2-acetylaminofluorene

RESULTS

Doses Producing Toxicity	Both doses of the notified chemical in the main study induced some toxic signs, such as reduction of spontaneous activity and ruffled fur. More severe toxic symptoms appeared more frequently with increasing dose. No deaths occurred.
Genotoxic Effects	The notified chemical did not, at any dose level, induce UDS in the hepatocytes of the treated animals as compared with concurrent controls and historical data.

Remarks - Results	Strong UDS responses were stimulated in the isolated hepatocytes of from animals treated with the positive controls, indicating that the test was functioning appropriately.
CONCLUSION	The notified chemical was non-genotoxic under the conditions of this *in vivo* UDS test system.
TEST FACILITY	RCC-CCR (2004b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Activated sludge from a domestic waste water treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biological oxygen demand (BOD)
Remarks - Method	Reference substance – Aniline Treatments - nutrient medium and inoculum - test substance (2.48 mg/L) - reference substance (2.06 mg/L) - toxicity control (test substance 2.42 mg/L and reference substance 2.12 mg/L). All treatments were done in duplicate.

RESULTS

Test substance		*Aniline*		*Toxicity Control*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
1	-2	1	0	7	19
5	40	5	50	14	21
7	40	7	54	21	24
12	44	12	73	28	47
14	43	14	77		
21	45	21	103		
28	42	28	104		

Remarks - Results	Under the test conditions the mean percentage biodegradation of the test substance reached in 40% after 5 days of incubation and 42% after 28 days. The percentage biodegradation did not exceed 60% within the 10 day window. According to the test guidelines the test item might be assumed to be inhibitory to activated sludge as <25% degradation was observed in the toxicity control after 14 days. On the basis of this the report suggests that the observed degradation of the test material may be an abiotic process rather than a biotic process. In addition, the method of analysis used in the test is not specific to the test material which has been shown to be rapidly hydrolysed (see above).
CONCLUSION	The notified chemical cannot be classed as readily biodegradable.
TEST FACILITY	IBACON (2002i)

8.1.2. Bioaccumulation

Due to the strong oxidising properties of notified chemical, it reacts very rapidly with any oxidisable substances including soil organic matter. In the course of oxidising reactions, notified chemical itself is reduced. In addition, notified chemical undergoes hydrolysis in the presence of water. Therefore, the substance notified chemical is not expected to be part of bioaccumulation processes.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE

METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi-static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - semi-static.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	acetonitrile
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	The stock solution (nominally 0.5 g/L) was prepared by dissolving 1 g the test substance in 20 mL of acetonitrile in 0.05 mol/L citrate buffer (pH 4) and filled up to 2 L with the buffer. Stock solutions were prepared daily. The concentration of the stock solutions was measured the concentration ranged between 0.48 and 0.41 g/L. Appropriate aliquots of the stock solution were used to prepare test media by diluting with test water. The test material concentrations in the test solutions were not determined. All reported results are related to the nominal concentrations of the test material. Water quality parameters of pH (4.9-7.2), temperature (16°C) and O_2 content (8.4-9.4 mg/L) were within normal limits throughout study.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*2 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	7	0/0	0/0	0/0	0/0	0/0
0.046		7	0/0	0/0	0/0	0/0	0/0
0.10		7	0/0	0/0	0/0	0/0	0/0
0.21		7	0/7	5/7	7/7	-/-	-/-
0.46		7	7/7	-/-	-/-	-/-	-/-
1.0		7	7/7	-/-	-/-	-/-	-/-

-/-: all fish dead

LC50	0.18 mg/L at 24 hours 0.15* mg/L at 48 hours 0.15* mg/L at 72 hours 0.15* mg/L (CI 0.10-0.21 mg/L) at 96 hours *Calculated as the geometrical mean value of the two concentrations with 0% and 100% mortality
NOEC (or LOEC)	0.10 mg/L at 96 hours
Remarks – Results	In the control and at the test concentrations, up to and including nominal 0.10 mg/L, all fish survived until the end of the test and no symptoms of intoxication were observed. At the next higher test concentration of 0.21 mg/L all test fish showed the following intoxication symptoms after 2 hours test duration: fish were mainly swimming at the water surface and showed strong ventilation. After 24 hours 5 of the 7 fish were dead, and after 48 hours all fish were already dead. At the two highest concentrations of 0.46 and 1.0 mg/L all fish were already dead after 2 hours.
CONCLUSION	The notified chemical is highly toxic to Rainbow Trout (*Oncorhynchus mykiss*).
TEST FACILITY	IBACON (2002e)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – semi-static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - semi-static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Acetonitrile
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The stock solution (nominally 0.5 g/L) was prepared by dissolving 1 g the test substance in 20 mL of acetonitrile in 0.05 mol/L citrate buffer (pH 4) and filled up to 2 L with the buffer. Stock solutions were prepared daily. The concentration of the stock solutions was measured the concentration ranged between 0.48 and 0.41 g/L. Appropriate aliquots of the stock solution were used to prepare test media by diluting with test water. The test material concentrations in the test solutions were not determined. All reported results are related to the nominal concentrations of the test material. Water quality parameters of pH (6.0-7.6), temperature (21°C) and O_2 content (8.4-9.4 mg/L) were within normal limits throughout study.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	-	20	0	0
0.046		20	0	0
0.10		20	0	0
0.21		20	0	0
0.46		20	20	20
1.0		20	20	20

LC50	0.21 < LC50 < 0.46 mg/L at 24 hours 0.21 < LC50 < 0.46 mg/L at 48 hours
NOEC	0.21 mg/L
Remarks - Results	After 48 hours of exposure the same results were obtained as after 24 hours. The report calculates the 48-hour LC50 to be 0.31 mg/L with 95% confidence limits from 0.21 to 0.46 mg/L using the geometric mean of the NOEC and the LOEC concentration (which in this case resulted in 100% immobility). The 48-h NOEC (highest concentration tested without toxic effects after 48 hours) of notified chemical was 0.21 mg/L, since no significant immobilization rate and no other signs of intoxication were observed in the test animals at up to and including this test concentration.
CONCLUSION	The notified chemical is highly toxic to *Daphnia magna*.
TEST FACILITY	IBACON (2002f)

8.2.3. 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	Green algae (*Scenedesmus subspicatus*)
Exposure Period	72 hours
Concentration Range	0.046, 0.10, 0.21, 0.46 and 1.0 mg/L (nominal)
Auxiliary Solvent	Acetonitrile

Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	
Remarks - Method	The test was conducted at 23ºC over a 72 hour period under static conditions The stock solution (nominally 0.5 g/L) was prepared by dissolving 1 g the test substance in 20 mL of acetonitrile in 0.05 mol/L citrate buffer (pH 4) and filled up to 2 L with the buffer. Appropriate aliquots of the stock solution were used to prepare test media by diluting with test water. Water quality parameters of pH (5.9-6.0 at the start of the test and 8.3-9.7 at the end of the study) and temperature (23°C) were within normal limits throughout study.

RESULTS

Biomass		*Growth*	
EC50	NOEC	EC50	NOEC
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
0.39	0.10	1.13	0.10

Remarks - Results	The test item had a statistically significant inhibitory effect on the growth of *Scenedesmus subspicatus* after the exposure period of 72 hours at the nominal concentration of 0.21 mg/L. Thus, this test concentration was determined as the 72-hour LOEC (lowest concentration tested with toxic effects). The 72-hour NOEC was determined as the nominal concentration of 0.10 mg/L, since up to and including this test concentration both the mean biomass and the mean growth rates of the algae were statistically not significantly lower than in the control.
CONCLUSION	The notified chemical is highly toxic to algae.
TEST FACILITY	IBACON (2002g)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	
Exposure Period	3 hours
Concentration Range	10, 32, 100, 320 and 1000 mg/L
Remarks – Method	Activated sludge samples from a sewage plant were incubated with the test material, together with two controls containing no test compounds. The test substance was run at five different concentrations and the reference compound in triplicate. Vessels were aerated during the tests, and O_2 consumption rates were monitored. Temperature was maintained at 18-20°C. Duplicate controls were run in parallel. Reference substance – 3,5-dichlorophenol Rate of respiration was determined after 30 minutes and 3 hours contact. Total water hardness – 100 mg/L $CaCO_3$.
RESULTS	
IC50	44 mg/L
NOEC	<10 mg/L
Remarks – Results	In comparison to the inoculum controls, the respiration rate of the

activated sludge was slightly inhibited by 6.6% at the lowest nominal test concentration of 10 mg/L. At the next higher concentrations of nominal 32 and 100 mg/L the respiration rate was inhibited by 42.6% and 75.4% respectively. At the test concentration of 320 mg/L an inhibition rate of 96.6% was determined and at the highest nominal test concentration of 1000 mg/L the inhibition was 100%. Based on the measured inhibition rates, the 3-hour EC_{50} was determined to be 44 mg/L with 95% confidence limits from 38 to 52 mg/L. The IC50 for the reference substance was 6.9 mg/L which is the accepted range of 5-30 mg/L.

CONCLUSION The notified chemical may be considered slightly toxic to activated sludge Mensink *et al.* 1995).

TEST FACILITY IBACON (2002h)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is to be used as a sanitiser that is likely to result in the disposal of the majority of the manufacture volume of the notified chemical through the sewage system. This discharge will occur in a dispersed manner across Australia. A small amount may be consigned to landfill as residues in containers.

The notified chemical is relatively soluble in water and is expected to readily hydrolyse in natural waters at environmental pH values. The notified chemical failed the ready biodegradability test and was shown to be slightly toxic to micro-organisms. However, the analytical method used, BOD, in the biodegradation study would have been affected by the toxicity of the notified chemical and was not specific for the notified chemical and the toxicity of the chemical. The notified chemical is readily hydrolysed and is strongly oxidising. Hence, the degree of degradation measured in the test is unlikely to reflect the true amount of primary degradation the notified chemical has undergone throughout the study. When disposed in landfill the chemical can be expected to become associated with soil and sediment and will rapidly degrade through abiotic processes. The product of the hydrolysis is known to be readily biodegradable and is much less toxic to aquatic organisms (Verschueren 1996).

Predicted environmental concentration (PEC) have been calculated as follows assuming the entire manufacture volume of the notified chemical is discharged to the sewer. As a worst case it has been assumed that none of the chemical is removed during sewage treatment. As the notified chemical is hydrolysable and strongly oxidising and is expected react in the sewage treatment and hence removed from the effluent. This is represented by the 90% removal assumed during passage through the sewage treatment plant (STP), the true removal rate through reaction is unclear and possibly even higher.

Amount in effluent entering sewer	10,000 kg			
Number of days	365			
National population	20.1 million			
Litres per person	200 L			
PEC_{sewer}	7 µg/L			
Removal by sewage treatment plant (STP)	0%		90%	
PEC (µg/L)	7		0.7	
Receiving waters	Ocean	River	Ocean	River
Dilution factor	1:10	1:1	1:10	1:1
PEC (µg/L)	0.7	7	0.07	0.7

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate the notified chemical is highly toxic to fish daphnia and algae and slightly toxic to micro-organisms. The most sensitive species is fish,

where the 96 h LC50 is 0.15 mg/L. Acute results are available for 3 trophic levels, so it is applicable to apply an assessment factor of 100 to the most sensitive species (fish), thus the predicted no effect concentration (PNEC) is 1.5 µg/L.

9.1.3. Environment – risk characterisation

The risk of the release of all of the manufactured notified chemical can be estimated by determining the aquatic risk quotient (RQ = PEC/PNEC).

Removal by STP	PEC	PNEC	Risk Quotient (RQ)
		Ocean	
0%	0.7 µg/L	1.5 µg/L	0.5
90%	0.07 µg/L	1.5 µg/L	0.05
		River	
0%	7 µg/L	1.5 µg/L	5
90%	0.7 µg/L	1.5 µg/L	0.5

The above risk quotients indicate an acceptable risk (RQ <1) to aquatic organisms in all cases except for river discharge with 0% removal through sewage treatment. Given the reactivity of the chemical this situation will not arise. Further only 25% of Australian sewers discharge to fresh water, lowering the RQ to 1.25.

The notified chemical is not likely to present a risk to the environment when it is stored, transported, used, recycled and disposed of in the proposed manner.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical formed *in situ* in the product KX-6049, and is present at relatively low concentrations (<1%). During manufacture the raw materials are mixed, then packaged. The notified chemical is generated after seven days standing in sealed containers, where it is present at <1% in KX-6049. Nonetheless, caution is required when handling KX-6049 at all stages, due to the corrosive nature of the formulation.

The primary routes of exposure to the notified chemical will be dermal or ocular, during its manufacture and during its use. To minimise exposure to KX-6049 and the notified chemical, all workers will wear appropriate personal protective equipment (PPE). Manufacturing workers are required to wear splash-proof safety goggles and face shield, safety boots, appropriate protective clothing and equipment to prevent skin or eye contact with the product. Laboratory workers involved in quality control testing, as part of good laboratory practice, are required to wear laboratory coats, safety goggles, nitrile gloves and safety boots. Other workers (eg warehouse, storage and transport workers) would not be exposed to the notified chemical, as all handling is of sealed containers. Exposure for these workers therefore could only occur where an accident causes rupture of containers containing the notified chemical.

Workers are unlikely to experience inhalation exposure to the notified chemical, as it has a low vapour pressure, and is formed in aqueous solution. Oral exposure to the notified chemical should not occur under normal use, given appropriate work hygiene practices.

During the use of sanitising solutions on food contact and non-food contact surfaces, the notified chemical is diluted significantly, such that exposure could only occur with concentrations in the order of <0.0026%. End users of KX-6049 are advised on the label and in the MSDS for the product to wear appropriate PPE. The greatest exposure to the notified chemical will be when handling open containers of KX-6049 during the preparation of sanitising solutions, where the chance of exposure is similar to that for manufacturing workers.

Therefore, given the appropriate use of PPE and appropriate working practices, workers are unlikely to be exposed to significant quantities of the notified chemical.

9.2.2. Public health – exposure assessment

The product KX-6049, containing the notified chemical, will not be available to the general public. It will be sold directly to customers in the food processing industry, where it will be used to sanitise food contact and non-food contact surfaces.

It is possible that the public could be exposed indirectly to very low levels of the notified

chemical, through foodstuffs that have come into contact with surfaces sanitised with KX-6049. However, it is unlikely that there will be any significant oral/dietary exposure to the notified chemical as a result of its use, as without stabilisation it rapidly degrades in contact with any surface, particularly in contact with water and metals.

Therefore, members of the public are unlikely to be exposed to any significant quantities of the notified chemical.

9.2.3. Human health – effects assessment

The toxicokinetic properties of the notified chemical are expected to be influenced by its high chemical reactivity to organic matter and its corrosive properties. In biological (water-based) systems, especially at higher pH values or in the presence of organic matter or trace metals such as copper, the notified chemical is rapidly hydrolysed to fatty acid and hydrogen peroxide. This conversion does not take place to 100% in biological systems as some oxidation of physiological substrates can also occur.

After oral uptake the notified chemical would quickly break down. Most would be converted in the mouth and throat and would not reach the stomach and intestine. Additionally, in simulated stomach contents, the notified chemical has been shown to degrade rapidly (t½ 1-30 mins depending on content) – implying that even were it was ingested, it would be broken down before significant absorption could occur (PTRL Europe 2004b). If the intestine was reached, and toxic effects occur at all, they would most likely be due to local irritation of mucous membranes, as the notified chemical is a very potent irritant. The notified chemical has also been demonstrated to be unstable in simulated blood (serum in sodium chloride solution), with a half-life of <1 min at room temperature or 36ºC (PTRL Europe 2004a).

Due to the high reactivity of the notified chemical with biological materials and its instability in a water-based environment, only local irritation or corrosion effects would be expected after dermal exposure. Dermal absorption would not be expected.

The degradation products of the notified chemical are unlikely to cause significant toxicity but are likely to be irritant. The fatty acid would be either integrated into body fat or converted by β-oxidation to acetylCoA and used as an energy source in the mitochondria. Hydrogen peroxide would be either enzymatically or non-enzymatically converted, mainly into water and oxygen.

The notified chemical showed low acute oral toxicity in rats up to the maximum dose of 2000 mg/kg bw, consistent with the expected toxicokinetic properties. Acute toxicity via the other routes was not tested.

Based on in-vitro testing, the chemical is predicted to be corrosive to eyes and skin. Confirmation of the dermal irritation potential was obtained from the skin sensitisation study, where concentrations of 25% and 50% produced slight to severe irritation. These results are consistent with the known oxidising properties of organic peroxides.

There was no evidence of sensitisation in an adjuvant test on guinea pigs.

Repeated dose testing was not performed, on the basis that systemic exposure to the notified chemical is not likely to occur.

Three *in vitro* and two *in vivo* genotoxicity tests have been performed on the notified chemical. Of these, a bacterial reverse mutation test showed mutagenic potential and an in vitro chromosome aberration test showed clastogenicity. Both positive results occurred only in the absence of metabolic activation. An in vitro mammalian gene mutation test was negative, as were the in vivo mouse micronucleus test and the in vivo unscheduled DNA synthesis assay. It has been speculated that the mutagenicity occurs indirectly, as a result of the notified chemical inducing oxidative stress effects on cultured cells (SCC (2005)). Negative results in the in vivo tests may reflect the likelihood that the notified chemical was degraded before reaching the test target organs. Based on the available data, the chemical would not be classified for genotoxicity.

No information was available on possible health problems or adverse symptoms occurring in humans exposed to the notified chemical.

Based on the available data, the notified chemical is classified as a hazardous substance with risk phrase R35 – Causes severe burns, in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

Other important hazards to health for organic peroxides are the potential for fire and explosion. The notified chemical was not sensitive to shock or friction in a test for explosive properties carried out to EC guidelines. Its flash point is 88ºC, and it is pyrophoric upon contact with air at room temperature. It is not flammable in contact with water. It undergoes a strong exothermic degradation upon heating, beginning at 50ºC, and cellulose cloths soaked in the notified chemical were found to be subject to spontaneous ignition at room temperature (24ºC). The physico-chemical hazards of the notified chemical as manufactured and supplied would be reduced because it is present at low concentration.

9.2.4. Occupational health and safety – risk characterisation

The notified chemical has been shown to be corrosive to skin and mucous membranes (i.e., eyes), so the potential hazard to workers is significant. The only likely routes of exposure for workers handling the notified chemical are likely to be dermal and ocular.

However, at the concentration at which the notified chemical is present in the product KX-6049 (< 1%), reduced toxicological effects and therefore reduced risk is expected to result from dermal or ocular exposure to it specifically (although the product KX-6049 is a hazardous in its entirety). In addition, end users will use KX-6049 greatly diluted in water (to 0.0026% v/v or less) for sanitising solutions, so the potential effect the skin and eyes of workers from the notified chemical is further reduced where exposure occurs to these very low concentrations.

Exposure to the product or diluted product should only occur as a result of spills and splashes, and these should not occur when good work practices are implemented. To safeguard against accidental exposure, the appropriate use of PPE should eliminate any risk to workers handling the notified chemical.

Precautions in formulation, storage, transport and end-use to minimise the risk of fire from reactive peroxides are also needed to ensure the safety of workers.

During its intended use, and in case of unintentional spills, the notified chemical will decompose to form hydrogen peroxide. It may be necessary to provide respiratory protection against this decomposition product.

9.2.5. Public health – risk characterisation

The public is not likely to be exposed to any significant concentrations of the notified chemical. Accidental exposure (eg as a result of an industrial accident) is possible, but unlikely.

The most likely public exposure is through foodstuffs that have come into contact with sanitising solutions containing the notified chemical during processing. The European Commission (EC) have approved the notified chemical and similar chemicals for direct use on food in poultry processing (EC, 2003). The conclusion of the EC was that the toxicological risk to the public following ingestion of food treated with these sanitisers is negligible. The levels of chemical residue in food through residual sanitiser on equipment would be even lower, therefore the risk to the public in this scenario would also be lower.

Overall the risk to the public is considered very low because of very low expected exposure.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

C: R35- Causes severe burns.

It should be noted that based on physico-chemical testing of the notified chemical and its chemical class, additional risk phrases would also apply.

and

As a comparison only, the classification of the notified chemical for human health and the

environment 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. Classification for physico-chemical hazards has not been included.

	Hazard category	*Hazard statement*
Acute toxicity	5	May be harmful if swallowed (oral)
Skin corrosion/irritation	1	Causes severe skin burns and eye damage
Chronic hazards to the aquatic environment	1	Very toxic to aquatic life with long-lasting effects.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as a component of sanitising solutions for food processing equipment.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant. ***(Label claims to be addressed by notifier).***

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR) should consider the following health hazard classification for the notified chemical:

  - R35- Causes severe burns.
  - S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
  - S28- After contact with skin, wash immediately with plenty of water.
  - S36/37/39- Wear suitable protective clothing, gloves and eye/face protection.

- S45- In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).

- Use the following health risk phrases for products/mixtures containing the notified chemical:
  - Conc ≥ 10% R35
  - 5% ≤ conc < 10% R34
  - 1% ≤ conc < 5% R36/37/38

- The notified chemical should be classified as follows under the ADG Code:
  - Class 5.2 Organic Peroxides, subsidiary risk Class 8 Corrosive.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical:
  - Manufacture of the chemical in closed systems
  - Transfer procedures should be automated where possible.
  - Exhaust ventilation should be used when the product containing the notified chemical is repacked or dispensed.

- Employers should implement the following safe work practices to minimise occupational exposure and ensure safety during handling of the notified chemical as introduced, and in the product as supplied to end-users
  - Avoid spills and contamination of the product containing the notified chemical
  - Wash spills from protective clothing promptly.
  - Dispose of cleaning rags safely.
  - Do not allow the product containing the notified chemical to dry on clothing or combustible material, in order to avoid fire.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as diluted for end-use:
  - Avoid generation of aerosols during end-use

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - During manufacture packaging and dilution: elbow length impervious gloves, chemical goggles or face-shield, safety boots and protective clothing
  - If inhalation exposure could occur, appropriate respiratory protection.
  - Protection from skin and eye contact with the final diluted product during end-use.

  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.
  - The MSDS should be revised to include the precautions in these recommendations.

- 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.
  - The notifier should consult with the appropriate State OHS authority to ensure label and MSDS compliance with legislation.

- The label for products containing the notified chemical should be prepared in accordance with the Australian Dangerous Goods Code and the NOHSC *NOHSC National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]*.
  - Label claims should be consistent with those applicable to industrial chemicals.

Environment

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
  - Do not allow material or contaminated packaging resulting from spills to enter drains, sewers or water courses.

Disposal

- The notified chemical should be disposed of to landfill in accordance with State/Territory waste disposal regulations.

Storage

- The following precautions should be taken by the manufacturer and end-users of the product containing the notified chemical regarding storage of the notified chemical:
  - Store in a cool place away from incompatible or combustible materials.
  - Keep containers closed to avoid contamination.

Emergency procedures

- Spills/release of the notified chemical should be handled by containment to prevent run-off sorbed onto an absorbent non-combustible material (soil, sand or other inert material). Collect and seal in properly labelled containers for disposal. Do not allow material to contaminate ground, groundwater or waterways. Prevent product from entering drains or stormwater system.
- Suitable protective equipment should be worn in the case of a spill/release, including respiratory protection against the decomposition product hydrogen peroxide.
- Contaminated material should not be re-used.

Transport and Packaging

- The Dangerous Goods classification of formulations containing the notified chemical should be established and should be transported and packaged consistent with the provisions of State and Territory legislation.

12.1. Secondary notification

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(1) of the Act; if
  - the notified chemical is introduced at concentrations above 1%
  - the use of the notified chemical changes.

or

(2) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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