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October 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in Kuriverter IK-110

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 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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1490	Pacific Environment Operations Pty Ltd	Chemical in Kuriverter IK-110	ND*	< 500 tonnes per annum	Slime control agent for Reverse Osmosis water treatment systems

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

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

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

Environmental risk assessment
Based on the PEC/PNEC ratio and the assessed use pattern, the treated discharge containing the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

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

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the product containing the notified chemical as introduced:
  - Coveralls
  - Safety goggles
  - Gloves

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures

consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

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

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a slime control agent for reverse osmosis water treatment systems, or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Pacific Environment Operations Pty Ltd (ABN: 86 127 101 642)
Suite 1, Level 1
146 Arthur Street
NORTH SYDNEY NSW 2060

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, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, use details, import volume, and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: melting point, vapour pressure, water solubility, partition coefficient, dissociation constant, flash point, skin irritation, eye irritation and skin sensitisation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Japan (2004)
Taiwan (2012)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Kuriverter IK-110 (contains the notified chemical at < 15% concentration in aqueous solution)

OTHER NAME(S)
Kurita KV IK-510 (contains the notified chemical at < 15% concentration in aqueous solution)
Kurita F-R110 (contains the notified chemical at < 15% concentration in aqueous solution)

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference IR and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: slightly yellow/brown transparent liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -16 °C*	(M)SDS
Boiling Point	107 °C at 102.91 kPa*	Measured
Density	1,289 kg/m^3 at 20 °C*	Measured
Vapour Pressure	4.07 x 10^{-21} kPa at 25 °C	Calculated (MPBPVP v1.43)
Water Solubility	Not determined	Expected to be highly water soluble based on the presence of hydrophilic functional groups in the chemical structure and use in aqueous systems
Hydrolysis as a Function of pH	Not determined	Not expected to hydrolyse significantly under ambient environmental conditions (pH 4 – 9)
Partition Coefficient (n-octanol/water)	Not determined	Not expected to significantly partition to n-octanol due to its expected high water solubility
Adsorption/Desorption	log Koc = -0.04, 0.3, 0.05, 0.3,	Measured

Property	Value	Data Source/Justification
	-0.1 for A, B, C, D, E soil, respectively*	
Dissociation Constant	Not determined	The notified chemical is a salt and is expected to be ionised at a pH range of between 4 – 9
Flash Point	Not determined	Introduced as an aqueous solution
Flammability	Not flammable in contact with water*	Measured
Autoignition Temperature	> 550 °C*	Measured
Explosive Properties	Not explosive*	Measured
Oxidising Properties	Not oxidising*	Measured

*For product containing the notified chemical at < 15% concentration

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

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

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a component of an aqueous product at < 15% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 300	< 300	< 500	< 500	< 500

PORT OF ENTRY
Melbourne, Sydney, Brisbane, Adelaide and Perth

TRANSPORTATION AND PACKAGING
The product containing the notified chemical at < 15% concentration will be introduced in 20 kg plastic drums and 1000 L IBCs. The product will arrive by ship and then be transported by road and rail.

USE
The notified chemical will be used as a slime control agent in Reverse Osmosis water treatment systems.

OPERATION DESCRIPTION
The product Kuriverter IK-110 containing the notified chemical at < 15% concentration in aqueous solution will be introduced to RO water treatment systems either manually using drum pumps and scales or through direct attachment of the import containers to an automated system. Recommended dosage patterns of Kuriverter IK-110 are intermittent 20-40 mg/L or continuous 10-20 mg/L for maintaining a cleansed system, or up to 40 mg/L (in extreme cases) over 3 hours to remove existing fouling. Fresh water and seawater systems are expected to use the same dosage concentrations.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS

Transport and storage workers may be exposed to the notified chemical at < 15% concentration only in the unlikely event of an accident or spill.

Workers at water treatment plants may be exposed (dermal and ocular) to the notified chemical at < 15% concentration when transferring the product containing the notified chemical to the RO water treatment system. Inhalation exposure is not expected given the low vapour pressure of the notified chemical. The stated use by the notifier of PPE is expected to minimise exposure.

6.1.2. Public Exposure

All residue concentrations of the notified chemical are expected to be removed from the process prior to discharge. The notifier states that if the notified chemical leaks to the permeate water at > 1 ppm due to, for example, deterioration of the RO membrane or mechanical difficulties, users would normally stop the RO system as the target water quality cannot be achieved. Therefore, public exposure to the notified chemical is expected to be negligible.

6.2. Human Health Effects Assessment

The notified chemical cannot be isolated. Therefore the results from toxicological investigations conducted on the product containing the notified chemical at < 15% concentration (similar to that to be introduced into Australia) were provided and are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rat, repeat dose oral toxicity – 90 days.	LOAEL = 80 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration	non genotoxic

Toxicokinetics.

The notified chemical is a salt and is highly water soluble hence dermal absorption is not expected unless the chemical has corrosive properties which may enhance penetration. Given the low molecular weight of the notified chemical absorption across the gastrointestinal tract may occur.

Acute toxicity.

The product containing the notified chemical at < 15% concentration is of low acute oral and dermal toxicity based on studies conducted in rats.

Irritation and sensitisation.

The product containing the notified chemical at < 15% concentration has a pH > 13 and is therefore classified as a corrosive. Given the product contains other chemical constituents known to have corrosive properties, it cannot be determined if the notified chemical has irritating properties. However based on chemical structure the notified chemical may present as an irritant.

Given the corrosive nature of the product based on pH, irritation and sensitisation studies were not conducted.

Repeated dose toxicity.

In a 90-day repeated dose oral toxicity study with a 14-day recovery period, rats were administered by gavage the product containing the notified chemical at < 15% concentration at doses of 80, 400 and 2000 mg/kg bw/day. No test substance related anatomical and histopathological changes were observed. However, a dose-dependent weight loss in males was observed during the treatment period in all dose groups. On this basis a NOAEL cannot be established. The lowest observed adverse effect level (LO(A)EL) was therefore established as 80 mg/kg bw/day.

Given the product contains other chemical constituents it cannot be determined that the notified chemical has contributed to the observed toxic effects in the repeated dose toxicity study.

Mutagenicity/Genotoxicity.

The product containing the notified chemical at < 15% concentration was negative both in a bacterial reverse mutation test and in an *in vitro* chromosome aberration test using human lymphocytes.

Health hazard classification
Based on the available information, the notified chemical cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Toxicological studies were only provided on the product containing the notified chemical at < 15% concentration as the notified chemical cannot be isolated. Based on these studies the product containing the notified chemical is corrosive. Given the product contains other chemical constituents known to have corrosive properties, it cannot be determined if the notified chemical has irritating properties. However, based on chemical structure the notified chemical may present as an irritant.

The notifier states that workers will wear PPE when handling the product containing the notified chemical at < 15% concentration to minimise exposure.

Therefore, provided the stated use of PPE is in place, the risk to workers from use of the notified chemical under the proposed use is not considered unreasonable.

6.3.2. Public Health
Under normal water treatment operations, public exposure to the notified chemical is not expected. In rare cases where the notified chemical may leak into the permeate water, public exposure to the notified chemical is not expected to exceed 1 ppm. Given negligible exposure to the notified chemical is expected, the risk to public health under the proposed use is not considered unreasonable. Furthermore, the product containing the notified chemical at < 15% concentration has been certified for drinking water treatment by NSF International (formerly the US National Sanitation Foundation).

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical is not manufactured or reformulated in Australia; therefore, release of the notified chemical to the environment is not expected from these activities.

RELEASE OF CHEMICAL FROM USE
The notified chemical is not expected to be released to the environment during use under normal operating conditions in reverse osmosis (RO) water treatment systems. In the event that the RO membrane has deteriorated or experienced mechanical failure, the system is expected to be stopped as the targeted water quality will no longer be achieved.

RELEASE OF CHEMICAL FROM DISPOSAL
The notified chemical in concentrate water discharged as wastewater from RO systems is expected to be released to wastewater treatment plants or directly discharged to the environment. It is expected that 100% of the total import volume of the notified chemical will be released to aquatic ecosystems. The empty containers with residues (0.5% of the total import volume) of the notified chemical are expected to be disposed of to landfill or collected by licensed waste contractors.

7.1.2. Environmental Fate
No environmental fate data were submitted for the notified chemical. The notified chemical is not expected to hydrolyse significantly under ambient environmental conditions but it is expected to be highly soluble in aquatic ecosystems. It is unlikely to persist in surface water based on its reactive nature. The supplied measured log K_{oc} values indicate that only a negligible amount of the notified chemical will be removed from wastewater by sorption to sludge or other solids during wastewater treatment at STPs. Thus, there is potential for the notified chemical to be released to surface waters. The notifier also indicated that the concentrate water, which contains the product containing the notified chemical, may be released directly to the environment. The notified chemical is not expected to bioaccumulate in aquatic life based on its expected high water solubility. The

notified chemical is expected to degrade in both the aquatic and terrestrial compartments through biotic and abiotic processes to form water, oxides of carbon and nitrogen, and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

Based on the reported use as a slime control agent in RO water treatment systems, 3.12 kg/day of the notified chemical will be discharged to a local sewage treatment plant (STP). It is conservatively assumed that the notified chemical will be released to a small size local STP with an average daily flow of 40 ML. The calculated PEC is 78 µg/L.

The notifier has indicated that the concentrate water containing the product, which contains the notified chemical, discharged from the RO treatment system may be released into the environment. However, the flow diagram provided by the notifier indicates that it will be pH adjusted (neutralised) before release to the environment. Ecotoxicological endpoints for the neutralised notified chemical were calculated using ECOSAR (v1.11). The ECOSAR results indicate that this chemical is not expected to be toxic to aquatic organisms.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted for the notified chemical. The results from ecotoxicological investigations conducted on a product containing the notified chemical at < 15% concentration are summarised in the table below. Details of the studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)	LC50 = 52 mg/L	Harmful to fish
Daphnia Toxicity (48 h)	EC50 = 59.1 mg/L	Harmful to aquatic invertebrates
Algal Toxicity (72 h)	E_rC50 = 62.8 mg/L	Harmful to algae

The product containing the notified chemical is harmful to fish, aquatic invertebrates and algae. On the basis of the acute toxicity data of the product containing the notified chemical, the product is expected to be harmful to aquatic organisms.

The product contains < 15% of the notified chemical as well as other chemical constituents. Consequently, it cannot be confidently assumed that the observed effects (toxicities) of the product can be attributed solely to the concentration of the notified chemical. Therefore, the observed effect (toxicity) of the notified chemical (< 15% concentration in the product) in the final product has not been adjusted to reflect the effect of the actual 100% concentration of the notified chemical. Therefore, Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009), the notified chemical has not been formally classified.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified chemical has been calculated and is presented in the table below. The PNEC is calculated based on the endpoint for the most sensitive species (Fish, LC50) for the product containing the notified chemical. Three acute ecotoxicity endpoints for aquatic species from three trophic levels are available. Therefore, an assessment factor of 100 has been used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish).	52	mg/L
Assessment Factor	100	
PNEC:	520	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	78	520	0.15
Q - Ocean:	7.8	520	0.015

The risk quotient (RQ) for discharge, containing the notified chemical, from a small size STP to the aquatic environment is < 1, which indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations based on its reported use pattern. The notified chemical is not expected to be bioaccumulative. Therefore, on the basis of the PEC/PNEC ratio, and the assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point 107 °C at 102.91 kPa

Method OECD TG 103 Boiling Point.
Remarks The test was conducted on a product containing the notified chemical at < 15% concentration. Boiling point was determined by Differential Scanning Calorimetry.
Test Facility SRICI Testing Centre (2012a)

Density 1289 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
Remarks The test was conducted on a product containing the notified chemical at < 15% concentration.
Test Facility SRICI Testing Centre (2012b)

Adsorption/Desorption – main test $\log K_{oc} = 0.11$

Method OECD TG 10:Adsorption-Desorption Using a batch Equilibrium Method (2000)

Soil Type	*Organic Carbon Content (%)*	*pH*	K_{oc}	*Log* K_{oc}
#A Loam	6.5	7.3	0.9	-0.04
#B Silt Loam	1.4	4.6	2.0	0.3
#C Silty Clay Loam	5.4	6.8	1.1	0.1
#D Silt Loam	1.4	7.8	2.1	0.3
#E Silt Loam	6.9	8.0	0.9	-0.1

Remarks The test was conducted on a product containing the notified chemical at < 15% concentration. The mean of the logarithmic adsorption coefficient ($\log K_{oc} = 0.11$) was reported for the test substance, indicating that the test substance was mobile in the soils tested. The notified chemical is expected to be mobile in soils.

Test Facility Key (2014a)

Flammability Not flammable in contact with water

Method GB/T 21619-2008 Dangerous goods – Test method for flammable solids which in contacting with water emit flammable gases
Remarks The test was conducted on a product containing the notified chemical at < 15% concentration.
The maximum evolution of flammable gas was 0.2 mL/g per hour. Therefore, based on this test results, the test substance is not classified as a substance which, in contact with water, emits flammable gases.
Test Facility SRICI Testing Centre (2012)

Autoignition Temperature > 550 °C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks The test was conducted on a product containing the notified chemical at < 15% concentration.
Test Facility SRICI Testing Centre (2012)

Explosive Properties Not explosive

Method GB/T 22232-2008 Test method for the thermal stability of chemicals by differential scanning calorimetry
Remarks The test was conducted on a product containing the notified chemical at < 15% concentration.

Test Facility SRICI Testing Centre (2012)

Oxidizing Properties Not oxidising

Method GB 19452-2004 Safety code for inspection of hazardous properties for dangerous goods of oxidising substances

Remarks The test was conducted on a product containing the notified chemical at < 15% concentration. The test substance in a 1:1 mixture with cellulose exhibited a pressure rise of less than 2070 kPa during the test period. Therefore, based on this test result, the test substance is not considered as an oxidising liquid.

Test Facility SRICI Testing Centre (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Product containing the notified chemical at < 15% concentration

METHOD: OECD TG 401 Acute Oral Toxicity.
- Species/Strain: Rat/Spague-Dawley
- Vehicle: Water
- Remarks - Method: Necropsy was not conducted

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 F/ 5 M	1,000	0/10
2	5 F/ 5 M	2,150	0/10
3	5 F/ 5 M	4,640	9/10
4	5 F/ 5 M	10,000	10/10

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: All animals dosed at 10,000 mg/kg bw died within 2 days of exposure. For animals dosed at 4,640 mg/kg bw, all male rats and 4 female rats died within 1 week of exposure. Clinical signs of toxicity in these exposure groups included dispirited, less active, and fluffy and lacklustre hair. There were no mortalities or clinical signs of toxicity in the 1,000 and 2,150 mg/kg bw dosage groups.
- Effects in Organs: Necropsy was not conducted
- Remarks - Results: The LD50 for male rats was determined to be 3160 mg/kg bw and that for female rats to be 3690 mg/kg bw.

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

TEST FACILITY: Ningbo (2013a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Product containing the notified chemical at < 15% concentration

METHOD: OECD TG 402 Acute Dermal Toxicity
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: Water
- Type of dressing: Semi-occlusive.
- Remarks - Method: No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 F/ 5 M	0	0/10
2	5 F/ 5 M	2000	0/10

- LD50: > 2000 mg/kg bw
- Signs of Toxicity - Local: All female animals exhibited erythema with subsequent incrustation. All signs of irritation were resolved at the 11-day observation period. Male rats did not show any signs of irritation.
- Signs of Toxicity - Systemic: No clinical signs of systemic toxicity were observed
- Effects in Organs: Gross anatomy was not conducted as no signs of toxicity were observed.
- Remarks - Results: From the Day 8 observation period, the bodyweight gain in male rats was significantly lower than animals of the control group whereas female rats

were significantly higher.

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

TEST FACILITY Ningbo (2013b)

B.3. Repeat dose toxicity

TEST SUBSTANCE Product containing the notified chemical at < 15% concentration

METHOD OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.

Species/Strain	Rats/Sprague Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Distilled water
Remarks - Method	Dose selection was based on the results of two previous studies:

1. After a single dose administration of a product containing the notified chemical at < 15% concentration at 5000 mg/kg bw all test rats died after 4 days exposure.

2. In a 28-day repeated dose oral toxicity study rats were administered by oral gavage with a product containing the notified chemical at < 15% concentration at doses of 200, 2000 and 3000 mg/kg bw/day. Rats dosed at 200 mg/kg bw/day showed no abnormalities. Rats dosed at 2000 mg/kg bw/day showed symptoms of decreased activity and filthy dorsal hair. Gross anatomy showed no abnormal changes. Rats dosed at 3000 mg/kg bw/day showed symptoms of listlessness, decreased activity, filthy dorsal hair and decreased appetite, and died after 5 days of exposure. The anatomy of dead animals showed thinning stomach and intestinal walls, congestion and thin liquid contents.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	10M/10F	0	0/20
low dose	10M/10F	80	2/20
mid dose	10M/10F	400	2/20
high dose	10M/10F	2000	2/20
control recovery	5M/5F	0	0/10
high dose recovery	5M/5F	2000	0/10

Mortality and Time to Death

In the low-dose group, one female animal was found dead at Day 24 and one male animal was euthanized on Day 58. In the mid-dose group, one male animal was found dead on Day 27 and a further male animal was euthanized on Day 66. In the high-dose group, one male animal was found dead on Day 59 and another male animal was found dead on Day 81. No abnormalities were seen in the above animals in gross anatomy and histopathological examination showed no test substance related histopatholgical changes. The cause of death was therefore not considered by the study authors to be test substance related.

There were no mortalities observed in the vehicle control group or in the recovery groups.

Clinical Observations

The body weights of male rats were significantly lower than the vehicle control group from week 2 (mid- and high-dose groups) and week 3 (low-dose group) onwards and showed a dose response. The body weights of

female rats in the high-dose group were significantly lower than the vehicle control group from week 6 onwards. The body weights of female and male rats in the high-dose group were lower than the vehicle control group at the end of the recovery period but showed a recovery trend.

Food consumption in all dose groups were similar to the vehicle control during the exposure and recovery periods, except for female rats in the mid- and high-dose groups, which showed significant lower food intake in weeks 2-4.

In the low-, mid- and high-dose exposure groups, significant clinical signs of toxicity included perioral and nasal wet, and fluffy and dry dorsal hair, the frequency of which increased with dose. These clinical symptoms persisted in the high dose recovery group. No significant clinical signs of toxicity were observed in the vehicle control group.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

In the high-dose group, males showed a significant decrease compared to the vehicle control group in globulin, glucose, triglyceride and lactase dehydrogenase and an increase in albumin and absolute lymph count. Females in the high-dose group showed a significant decrease in Ca and glucose, and an increase in P and total cholesterol.

In the mid-dose group, females and males showed a significant decrease compared to the vehicle control in triglyceride, and females showed a decrease in lactase dehydrogenase.

In the low-dose group, males showed a significant decrease compared to the vehicle control group in P, total cholesterol and triglyceride. Females in the low-dose group showed a significant decrease in glucose and triglyceride.

At the end of the recovery period, female rats of the high-dose group showed a significant decrease compared to the vehicle control in total protein, albumin and urea nitrogen and male rats showed an increase in lactase dehydrogenase.

Urinalysis showed no test substance related changes.

Effects in Organs

At the end of the exposure period, there were changes in the absolute organ weights compared to the vehicle control in the heart and liver in all exposure groups. There were also changes observed in absolute organ weights in the following organs: kidney (high-dose), thymus (high-dose), spleen (high-dose) and epididymis (low-dose). The changes in organ weights were usually accompanied by a body weight decrease. At the end of the recovery period, changes in organ weights were still observed in the heart and kidney. Histopathological examination showed no test substance related histopathological changes in these or in any other organs. The observed changes in organ weights were considered by the study authors to be associated with animal weight loss.

Remarks – Results

No test substance related anatomical and histopathological changes were observed. However a dose-dependent weight loss in males was observed during the treatment period in all dose groups. On this basis a NOAEL cannot be established.

CONCLUSION

The Lowest Observed (Adverse) Effect Level (LO(A)EL) was established as 80 mg/kg bw/day in this study, based on body-weight loss.

TEST FACILITY	Ningbo (2013c)

B.4. Genotoxicity – bacteria

TEST SUBSTANCE	Product containing the notified chemical at < 15% concentration
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98 and TA100

	E. coli: WP2uvrA
Metabolic Activation System	S9 from phenobarbital/5,6-benzoflavone induced rat liver
Concentration Range in Main Test	Test 1 – Plate incorporation procedure a) With metabolic activation: 156.3-5000 µg/plate b) Without metabolic activation: 39.1-5000 µg/plate Test 2 – Pre incubation procedure a) With metabolic activation: 78.1-5000 µg/plate b) Without metabolic activation: 39.1-2500 µg/plate
Vehicle	Water
Remarks - Method	No significant protocol deviations. A dose determination test was conducted at doses ranging from 6.86-5000 µg/plate in the presence or absence of metabolic activation. Positive controls *Without metabolic activation*: 2-(2-furyl)-3-(5-nitro-2-furyl) acrylamide and sodium azide *With metabolic activation*: 9-aminoacridine

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 1667	≥ 1250	> 5000	negative
Test 2		≥ 1250		negative
Present				
Test 1	≥ 5000	≥ 2500	> 5000	negative
Test 2		≥ 2500		negative

Remarks - Results	No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, at any dose of the test substance, either with or without metabolic activation. The positive controls gave satisfactory responses, confirming the validity of the test system.
CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Nippon (2011)

B.5. Genotoxicity – in vitro

TEST SUBSTANCE	Product containing the notified chemical at < 15% concentration
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Human
Cell Type/Cell Line	Lymphocytes
Metabolic Activation System	S9 from phenobarbital/5,6-benzoflavone induced rat liver
Vehicle	Physiological saline
Remarks - Method	No significant protocol deviations. Positive controls *Without metabolic activation*: mitomycin C *With metabolic activation*: cyclophosphamide

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 412, 588, 840*, 1201*, 1715*, 2450*	3 h	24 h
Test 2	0*, 36.8, 73.5, 147, 294*, 588*, 840*, 1201, 1715	24 h	24 h
Present			
Test 1	0, 412, 588, 840, 1201*, 1715*, 2450*, 3500	3 h	24 h

*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				
Test 1	≥ 1611	≥ 1715	> 2450	negative
Test 2	≥ 641	≥ 840	> 1715	negative
Present				
Test 1	≥ 2016	≥ 1715	> 3500	negative

Remarks - Results

The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

The test substance did not induce any statistically significant increases in the frequency of cells with aberrations.

CONCLUSION

The test substance was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY

Biosafety (2011)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Product containing the notified chemical at < 15% concentration
METHOD	JIS K 0102: 1998 Testing methods for industrial wastewater: Acute Toxicity Test – Static Test
Species	Japanese killifish (*Oryzias latipes*)
Exposure Period	48 hours
Auxiliary Solvent	Not reported
Water Hardness	46 mg $CaCO_3$/L
Analytical Monitoring	Not reporting
Remarks – Method	The test was conducted according to the guidelines above. No significant deviations from the test guidelines were reported. The above stated test guideline is very similar to OECD TG 203.

RESULTS

Nominal Concentration (mg/L)	*Number of Fish*	*Mortality (%)*	
		24 h	*48 h*
Control	10	0	0
10	10	0	0
100	10	0	70
1000	10	100	100

LC50	52 mg/L at 48 hours
NOEC	Not reported
Remarks – Results	All validity criteria for the test were satisfied. The 48-hour LC50 was calculated by applying the Doudoroff method. All results were based on nominal concentrations. The test substance contains < 15% of the notified chemical and other chemical constituents. Consequently, the resultant toxicity in this experiment may have been contributed to by all of the chemical constituents, including the notified chemical, in the product. Therefore, the observed effect (toxicity) of the notified chemical (< 15% concentration in the product) has not been adjusted to reflect the actual 100% concentration of the notified chemical.
CONCLUSION	The product containing the notified chemical is harmful to fish
TEST FACILITY	JFRL (2007)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Product containing the notified chemical at < 15% concentration
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	UPLC-PDA analysis
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

Nominal Concentration (mg/L)	*Number of D. magna*	*Cumulative % Immobilised*	
		24 h	*48 h*
Control	20	0	0
10	20	0	5
20	20	10	10
40	20	10	20
80	20	55	55
100	20	100	100

EC50	59.1 (53.8 – 64.9) mg/L at 48 hours
NOEC	Not reported
Remarks - Results	All validity criteria for the test were satisfied. The actual concentrations of the test substance were measured periodically at 0, 24 and 48 hours within the 48-h test period. However, the EC50 value was calculated based on the nominal loading rates as the toxicity cannot be attributed to a single component or mixture of components but to the test substance as a whole. Therefore, the observed effect (toxicity) of the notified chemical (< 15% concentration in the product) has not been adjusted to reflect the actual concentration of the notified chemical. The 48-hour EC_{50} was calculated by the trimmed Spearman-Karber method.
CONCLUSION	The product containing notified chemical is harmful to aquatic invertebrates
TEST FACILITY	Key (2014b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Product containing the notified chemical < 15% concentration
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Chlorella vulgaris* Beij.
Exposure Period	96 hours
Concentration Range	Nominal: 10, 20, 40, 80, and 100 mg/L
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	UPLC-PDA analysis
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

Biomass (72 h)		*Growth (72 h)*	
E_yC50 (mg/L)	*NOE_yC (mg/L)*	*E_rC50 (mg/L)*	*NOE_rC (mg/L)*
-	-	62.8	Not reported

Remarks - Results	All validity criteria for the test were satisfied. The actual concentrations of the test substance were measured periodically at 0, 24, 48, 72, and 96 hours within the 96-h test period. However, E_rC50 value was calculated based on the nominal loading rates as the toxicity cannot be attributed to a single component or mixture of components but to the test substance as a whole. The 72-hour E_rC_{50} was calculated by the trimmed Spearman-Karber method. The test substance contains < 15% of the notified chemical and other chemical constituents. Consequently, the resultant toxicity in this experiment may have been contributed by all the chemical constituents, including the notified chemical, in the product. Therefore, the observed effect (toxicity) of the notified chemical (< 15% concentration in the product) has not been adjusted to reflect the actual 100% concentration of the notified chemical.
CONCLUSION	The product containing notified chemical is harmful to algae
TEST FACILITY	Key (2014c)

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