File No: STD/1388

December 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Zinc, bis[(2S)-2-(hydroxyl-.kappa.O)propanato-.kappa.O]-, (T-4)-

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

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 SUBSTANCE	INTRODUCTION VOLUME	USE
STD/1388	Procter & Gamble Australia Pty Ltd	Zinc, bis[(2S)-2-(hydroxyl-.kappa.O)propanato-.kappa.O]-, (T-4)-	Yes	≤1.4 tonnes per annum	Component of toothpaste products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the data provided, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], with the following risk phrases:

R22 Harmful if swallowed
R36 Irritating to eyes

And

The classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2009) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Irritant	2A	Causes serious eye irritation
Acute toxicity	4	Warning: Harmful if swallowed
Environmental	Acute category 1	Very toxic to aquatic life
	Chronic category 1	Very toxic to aquatic life with long lasting effects

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 toothpaste products intended for use by adults and children aged 12 years and older at ≤2.5% concentration, the notified chemical is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio, comparison with Australian soil and water quality guideline limits and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia, should consider the following health hazard classification for the notified chemical:
  - Xn: R22 Harmful if swallowed
  - Xi: R36 Irritating to eyes

- Use the following risk phrases for products/mixtures containing the notified chemical:

- Conc. ≥25%: Xn; R22; R36;
- ≥20% Conc. <25%: Xi; R36.

- The Delegate (and/or the Advisory Committee on Chemicals Scheduling) should consider the notified chemical for listing on the SUSMP.

CONTROL MEASURES
Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical itself. However, these should be selected on the basis of all ingredients in the formulation.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

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

Public Health

- The following measures should be taken to minimise public exposure to the notified chemical:
  - The notified chemical should only be used at ≤2.5% in toothpastes intended for use by adults and children aged 12 years and older.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified 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(1) of the Act; if
  - the notified chemical is introduced in a form other than toothpaste products at ≤2.5%;
  - the concentration of the notified chemical exceeds or is intended to exceed 2.5% in toothpaste products;
  - the notified chemical is intended for use in toothpaste products for children (<12 years of age);

or

(2) Under Section 64(2) of the Act; if

- the function or use of the chemical has changed from a component of toothpaste products, or is likely to change significantly;
- the amount of chemical being introduced has increased from 1.4 tonnes per annum, 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.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Procter & Gamble Australia Pty Ltd (ABN: 91 008 396 245)
Level 4, 1 Innovation Road
Macquarie Park, NSW 2113

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints (exceptions: water solubility, adsorption/desorption), ready biodegradability, all human health endpoints (exceptions: acute oral toxicity, eye irritation and skin irritation).

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, Canada

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Puramex Zn (dihydrate of the notified chemical)

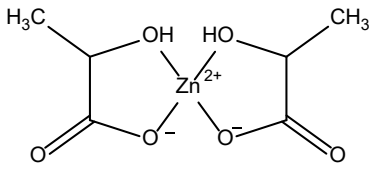
CAS NUMBER
63179-81-7

CHEMICAL NAME
Zinc, bis[(2S)-2-(hydroxyl-.kappa.O)propanato-.kappa.O]-, (T-4)-

OTHER NAME(S)
Zinc lactate

MOLECULAR FORMULA
$C_6H_{10}O_6Zn$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
243 Da

ANALYTICAL DATA
Reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY ≥99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 ºC AND 101.3 kPa: white crystalline/powder (dihydrate of the notified chemical)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	>200 ºC	MSDS
Bulk Density	900 kg/m^3	MSDS
Vapour Pressure	Not determined	Expected to be low
Water Solubility	~50 g/L at 20 ºC	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical is expected to dissociate to zinc (II) and lactate in water. The dissociated components of the notified chemical do not contain hydrolysable functionality and are not expected to hydrolyse under environmental conditions.
Partition Coefficient (n-octanol/water)	Lactic acid: log Pow = -0.62 at 20 ºC	Analogue, measured
Adsorption/Desorption	Zinc (II): log K_{oc} = 2.2 Lactate: log K_{oc} = -0.654	Analogue (EC, 2010) Predicted (KOCWIN v2.00, US EPA, 2009)
Dissociation Constant	Log K_1 = -2.22 at 25 ºC Log K_2 = -1.52 at 25 ºC	Measured
Particle Size	Not determined	Introduced only in formulated products
Flash Point/Flammability	Not determined	Introduced only in formulated products. Not expected to be flammable under conditions of use
Autoignition Temperature	Not determined	Introduced only in formulated products. Not expected to autoignite under normal conditions
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties

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. Strong oxidising agents should be avoided. Decomposition products include zinc oxide and oxides of carbon.

Dangerous Goods classification
Based on the limited submitted physical-chemical data in the above table, the notified chemical is not classified

according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be introduced as a component (≤2.5%) of toothpaste.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1	1.1	1.2	1.3	1.4

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Procter & Gamble Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The toothpaste products containing the notified chemical (at ≤2.5%) will be imported in tubes/containers suitable for retail sale and will be distributed within Australia by road.

USE
The notified chemical will be used as a component of toothpaste at ≤2.5% concentration.

OPERATION DESCRIPTION
The notified chemical will be imported as a component of toothpaste for use by the general public. Reformulation will not take place in Australia.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure
The notified chemical will not be manufactured or reformulated in Australia and hence occupational exposure will be limited to transport and storage workers. Such workers may come into contact with the notified chemical as a component of end-use products (at ≤2.5%) only in the event of accidental rupture of containers.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified chemical through the use of toothpastes containing it (at ≤2.5% concentration). The principal route of exposure will be oral. The notified chemical will only be used in toothpastes intended for use by adults and children aged 12 years and older.

Data on typical use patterns of toothpaste are shown in the following table (SCCS, 2010). For the purposes of the exposure assessment, Australian use patterns for toothpaste are assumed to be similar to those in Europe. An adult bodyweight of 60 kg has been used for calculation purposes. In addition, 20% systemic exposure has been assumed, based on buccal and/or gastrointestinal absorption (see Section 6.2 for further details). Using this data, the systemic exposure is estimated to be 0.011 mg/kg bw/day notified chemical (0.0029 mg Zn^{2+}/kg bw/day).

Product type	**Amount** (mg/kg bw/day)	**C** (%)	**RF**	**Daily systemic exposure** (mg/kg bw/day)
toothpaste	43.29	2.5	0.05	0.011

C = concentration; RF = retention factor

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 between 500 and 2000 mg/kg bw; harmful
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	irritating
Rabbit, eye irritation (low volume)	slightly irritating
Eye irritation – isolated chicken eye test	not severely irritating

Additional information on the expected health effects of the notified chemical is based on the European Union risk assessment report of an analogue of the notified chemical, zinc distearate, which also incorporates the assessment of an additional five zinc compounds (EC, 2004 and references there-in). This chemical is considered to be a suitable analogue for the notified chemical, based on the assumption that the zinc cation is the determining factor for the activities of zinc compounds. In the risk assessment of zinc distearate, it was assumed that all zinc compounds are changed, at least to some extent, to the ionic form. Therefore, the toxicity data in the assessment was used and expressed as the cation, irrespective of the compound tested.

Lactic acid is found naturally in several foods. In addition, it is used as a food additive in many types of foods with no limits placed upon its acceptable daily intake or levels in the food types.

Toxicokinetics, metabolism and distribution.
A regular exogenous supply of zinc is required to maintain the necessary physiological levels in the body. Homeostatic mechanisms are in place and include the regulation of gastrointestinal absorption and secretion.

The amount of zinc absorbed when administered via the oral route is influenced by a number of factors, including dietary ligands and the levels of zinc in the body. It is estimated that 20%-30% is absorbed in persons with adequate nutritional levels, with those that are deficient absorbing more and those with excessive zinc intake absorbing less (EC, 2004).

Little data on the extent of zinc absorption following dermal and inhalation exposure is available. However, it is suggested that following inhalation exposure, pulmonary absorption is possible (and/or that material will translocate to the gastrointestinal tract). In addition, dermal absorption through intact skin is likely to be low (~2%).

Following absorption, zinc is distributed to all tissues and tissue fluids and while it is primarily excreted in feces, it may also be excreted in urine, saliva, hair loss, sweat, and breast milk.

Acute toxicity.
The notified chemical was found to be harmful in an acute oral toxicity study in rats. No deaths were recorded following administration of the test substance at up to 500 mg/kg bw. However, at the next dosage level (2000 mg/kg bw), 8/10 animals died within 3 days of administration of the test substance. Therefore, the LD50 was considered to be between 500 and 2000 mg/kg bw. No acute dermal or inhalation toxicity data were provided for the notified chemical. However, it is reported that the acute toxicity of zinc following dermal administration is low (EC, 2003).

Irritation and Sensitisation.
The notified chemical was not a skin irritant in rabbits, when applied to intact and abraded skin.

The reports of three eye irritation studies conducted on the notified chemical were provided. In the first study, which was conducted according to OECD test guidelines, the notified chemical was determined to be at least an irritant to the eyes of rabbits. Noted effects included moderate corneal opacity, slight iritis, moderate redness, ischemic necrosis, severe swelling of the conjunctivae and severe ocular discharge. Due to the severity of the effects observed, the animals were killed following the 72 hour observation. This did not allow the reversibility of the effects to be determined. Although the corneal opacity and iridial inflammation scores did not warrant classification of the chemical as ‘R41 Risk of Serious of Damage to Eyes’, only as ‘R36 Irritating to Eyes’, the study authors indicated that the R41 classification was appropriate based on the severity of the effects observed, in-particular, the ischemic necrosis. In addition, the ocular lesions may not have reversed within the usual observation time (21 days), further supporting the likely R41 classification.

In the second study, the notified chemical was not severely irritating in an isolated chicken eye test. However, this may have been a false negative, based on the solid nature of the test substance. The study authors proposed that the difference in results between the *in vivo* and *in vitro* studies may have been due to the exposure method, *i.e.* instillation of a powder in the conjunctival sac *in vivo* versus direct corneal application *in vitro*. It is proposed that when applied to the conjunctival sac, the test substance may become entrapped and unable to be cleared.

In the third study, the eye irritancy effects of the chemical were studied in rabbits, using a low volume procedure (0.01 mL of the test substance was administered onto the cornea, as opposed to 0.1 mL into the conjunctival sac, as indicated by the test guideline). Under the conditions of the study, the notified chemical was determined to be slightly irritating to the eyes of rabbits, with noted effects including moderate-severe redness and swelling of the conjunctivae, ischemic necrosis, and slight-moderate ocular discharge. However, the scores did not warrant classification of the chemical as an eye irritant.

Based on the weight of evidence, the notified chemical is considered to be classified as an eye irritant.

No data on the skin sensitisation potential of the notified chemical was provided. However, based on data available for other zinc compounds, skin sensitisation is not expected.

Repeated Dose Toxicity.
No repeated dose toxicity studies on the notified chemical were provided. Several studies on zinc compounds have been conducted *via* the oral route, in both humans and animals. In the EU report of zinc distearate (EC, 2004), a NOAEL of 50 mg Zn^{2+}/day (0.83 mg/kg bw/day) from human studies was chosen for risk assessment purposes, based on noted effects at higher dosage levels, in particular disruption of copper homeostasis.

The Recommended Dietary Intake (RDI) for zinc is 12 mg (4.5 mg for children aged 1-3 years). Zinc lactate is a permitted form (FSANZ, 2000).

Mutagenicity.
No data on the mutagenicity potential for the notified chemical was provided. Several *in vitro* and *in vivo* studies on zinc compounds have been conducted, with variable results. The available data suggests that zinc has genotoxic potential *in vitro*, but that there is not a clear indication of genotoxicity *in vivo*.

Carcinogenicity.
Limited studies on the carcinogenicity potential of zinc compounds are available. It is noted in the EU report (EC, 2004) that zinc deficiency or supplementation may influence carcinogenesis, but that there is no evidence for a direct carcinogenic action of zinc.

Toxicity for reproduction.
In the EU report (EC, 2004), a NOAEL of >19.9 mg Zn^{2+}/kg bw/day was adopted for developmental toxicity in animals. It is noted that a zinc deficiency results in an impairment of fertility and foetal development. Therefore, zinc was determined not to be of concern with respect to reproductive toxicity in humans.

Health hazard classification
Based on the data provided, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:

R22 Harmful if swallowed
R36 Irritating to eyes

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
As exposure to the notified chemical will be limited to accidental exposure of transport and storage workers, the risk to workers associated with use of the notified chemical at ≤2.5% concentration in toothpastes is not considered to be unreasonable.

6.3.2. Public Health
The notified chemical is proposed for use by adults and children aged 12 years and older at ≤2.5% concentration in toothpaste. While the notified chemical is considered to be harmful to human health via the oral route, effects are not expected at the proposed usage concentration. Similarly, while the notified chemical

is classified as an eye irritant, ocular exposure is not expected from the proposed use.

The repeated dose toxicity effects of the notified chemical have not been determined. However, similar adverse effects to those observed in studies conducted on zinc and zinc salts, particularly with respect to disruption of copper homeostasis, may be expected.

Repeat dose toxicity potential was estimated by calculation of the margin of exposure (MoE) of the notified chemical using the exposure scenario of 0.0029 mg Zn^{2+}/kg bw/day (see Section 6.1.2) and an (internal) NOAEL of 0.17 mg/kg bw/day. Note that the (internal) NOAEL was determined by assuming 20% oral absorption of the NOAEL dose (0.83 mg/kg bw/day), which was established in toxicity studies involving zinc. Given that the NOAEL was derived from human data, a MoE ≥10 is considered acceptable to account for intraspecies differences. Using the abovementioned (internal) NOAEL, a MoE of 59 was estimated, and is thus considered acceptable. In considering the above assessment, it is also acknowledged that zinc will be systemically available from other sources (e.g. ingestion of food products), that there is a requirement for exogenous zinc intake, and that homeostatic mechanisms are in place to regulate zinc intake.

The intended use scenario for the notified chemical does not include use in toothpaste products for children aged <12 years, The systemic exposure level to the notified chemical is expected to be significantly higher in children than in adults and the recommended zinc daily intake level lower. Therefore, the notified chemical is not recommended for use in toothpaste products that are intended to be used by children. However, the estimated MoE is sufficiently high, such that the risk to children associated with incidental use of toothpaste products that are intended for use by adults, is not considered to be unreasonable.

Therefore, the risk to the public associated with the use of the notified chemical at ≤2.5% concentration in toothpaste is not considered to be unreasonable, when intended to be used by adults and children aged 12 years and older.

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, there will be no releases from these activities. Environmental release during importation, transport and distribution may occur as a result of accidental spills. However, in the event of a spill, release to the environment is expected to be minimal due to the limited capacity of individual packages and the typical semi-solid formulations of toothpaste products. In the event of a spill, the notified chemical should be contained, collected and disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be released to sewer in domestic situations across Australia as a result of its use in toothpaste products.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues in end-use containers are expected to be disposed of to landfill.

7.1.2. Environmental Fate

Following its use in Australia, the majority of the notified chemical will enter the sewer system. The notified chemical is expected to largely dissociate into inorganic zinc (II) and organic lactate components which are expected to follow different pathways during sewage treatment plant (STP) processes.

The majority of lactate would be expected to be released to environmental waters in STP effluent due to its high water solubility and low predicted adsorption coefficient. Lactate is not expected to readily hydrolyse in environmental conditions (US EPA, 2002) but is biodegradable (refer to Appendix C). In surface waters or in soils, lactate is expected to rapidly degrade to form water and oxides of carbon. Lactate is unlikely to bioaccumulate due to its low partition coefficient.

The majority of zinc is expected to partition to biosolids during STP processes and either be disposed of to

landfill or applied to agricultural soils. Small amounts may be released to surface waters in effluent. Zinc is an element and therefore cannot be biodegraded. The most important physicochemical factors affecting bioavailability of zinc in both terrestrial and aquatic systems are: pH, dissolved organic carbon (DOC), water hardness, competing ions, soluble ligands, and binding sites on solid phases (e.g., metal oxides in suspended matter, sulfides in sediments and anaerobic soils). However, long-term bioavailability of zinc in soil is influenced by mineralization processes, such as lattice penetration, which result in irreversible binding of zinc. Zinc is an essential element and many organisms are capable of regulating internal zinc concentrations. The concentration at which zinc is homoeostatically regulated is species-specific and the external zinc concentration at which regulation breaks down depends on both intrinsic (e.g., species) and extrinsic (e.g., temperature) factors. Accumulation of zinc to meet physiological requirements can be mistaken for trophic transfer. However, zinc is not biomagnified (WHO, 2001).

A small amount of the notified chemical may be disposed of to landfill in end-use container residues. The notified chemical is expected to degrade via biotic and abiotic processes in landfill to form water and oxides of carbon and zinc.

7.1.3. Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentrations (PECs) have been separately calculated for the two dissociated components of the notified chemical due to the expected different pathways during sewage treatment plant (STP) processes. The worst-case PECs have been calculated assuming that all of the imported quantity of notified chemical will be released to sewer.

Lactate

Lactate - Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,400	kg/year
Lactate content of notified chemical	73.08%	
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,023.12	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.80	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.62	µg/L
PEC - Ocean:	0.06	µg/L

Lactate is not expected to significantly partition to biosolids in STPs due to its high water solubility.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.62 µg/L may potentially result in a soil concentration of approximately 4.132 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 20.66 µg/kg and 41.32 µg/kg, respectively.

Zinc (II)

Metals are efficiently removed during STP processes, with some STPs capable of up to 99.9% efficiency (EC, 2010). For the worst-case calculation of the PEC for the aquatic compartment, a conservative 90% of zinc (II) from the notified chemical is estimated to be removed by adsorption and flocculation during STP processes before discharge to surface waters on a nation wide basis.

Zinc (II) - Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,400	kg/year

Zn (II) content of notified chemical	26.92%	
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	376.88	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	1.03	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	**Mitigation**
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.02	µg/L
PEC - Ocean:	0.002	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an increase to average zinc concentration in biosolids of 2.055 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.014 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 0.07 mg/kg and 0.14 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The zinc from the notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.023 µg/L may potentially result in a soil concentration of approximately 0.1522 µg/kg. Assuming accumulation in soil for 5 and 10 years under repeated irrigation, the concentration of zinc (II) due to the notified chemical in the applied soil in 5 and 10 years may be approximately 0.7610 µg/kg and 1.522 µg/kg, respectively.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 (96 h) = 73 mg/L	Harmful to fish
Daphnia Toxicity	EC50 (48 h) = 6.3 mg/L	Toxic to aquatic invertebrates
Algal Toxicity		
Low hardness water	EC50 (72 h) = 520 µg/L	Very toxic to algae
(15.3 mg $CaCO_3$/L)	NOEC (72 h) = 32 µg/L	Very toxic to algae with long lasting effects

Zinc is an essential element and aquatic organisms are known to bioconcentrate zinc from water. While most aquatic organisms internally regulate zinc concentrations, elevated levels of zinc in water can overwhelm homeostasis mechanisms leading to toxicity. The notified chemical is a readily soluble metal compound. Zinc (II) is not expected to rapidly partition from the water column in surface waters due to its solubility. Therefore, the notified chemical has been classified in accordance with Annex 9, Classification of metals and metal compounds, A9.7.5.3.2.2., under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009ab). The notified chemical is very toxic to algae, toxic to aquatic invertebrates and harmful to fish and is formally classified as 'Acute Category 1: Very toxic to aquatic life'. On the basis of the acute endpoint for algae toxicity, the notified chemical is formally classified as 'Chronic Category 1: Very toxic to aquatic life with long lasting effects'.

The predicted ecotoxicity endpoints for lactate exceed 2000 mg/L for all aquatic trophic levels with the lowest endpoint being for green algae (ChV = 2093 mg/L, ECOSAR v1.00, neutral organics – acid, US EPA, 2009). The observed toxicity of the notified chemical is considered to be largely attributable to the dissociated zinc (II) ion.

7.2.1. Predicted No-Effect Concentration

Due to the different exposure pathways of the dissociated components of the notified chemical, and as toxicity of the notified chemical is considered to be largely attributable to the zinc (II) ion, a separate PNEC for the aquatic compartment is calculated for zinc (II) and lactate.

Lactate

The PNEC for lactate is calculated using the predicted ChV for green algae. An assessment factor of 50 was considered appropriate in this case as lactate is expected to be within the domain of the model and a ChV (not a NOEC) is used.

Lactate - Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ChV (Alga)	2,093	mg/L
Assessment Factor	50	
PNEC:	41.86	mg/L

Zinc (II)

The hazard data for the notified chemical indicates that, even after allowing for the mitigating effects of typical hardness of surface waters, the most sensitive ecotoxicological endpoint is for algae. The PNEC is calculated for the worst-case using the reported NOEC for algae in low hardness water, which has been converted to the nominal concentration of zinc (II) to allow for comparison with the PEC. An assessment factor of 50 was considered appropriate in this case and was applied since there is a chronic endpoint from one species which has been provided and is used.

Zinc (II) - Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (Alga)	9	µg Zn/L
Assessment Factor	50	
PNEC:	0.18	µg Zn/L

7.3. Environmental Risk Assessment

The notified chemical is expected to dissociate into zinc (II) and lactate in water. Therefore, as the majority of the notified chemical is expected to be released to sewers, the risk assessment considers the exposure and hazard of the two components separately. Based on the above PEC and PNEC values, the following Risk Quotients (Q) have been calculated:

Lactate Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.62	41860	<<0.001
Q - Ocean:	0.06	41860	<<0.001

Although lactate is expected to have exposure to the aquatic compartment due to its high water solubility and partitioning characteristics in STPs, it is considered not harmful to aquatic life and is not expected to reach ecotoxicologically relevant concentrations. The risk quotient (PEC/PNEC) is well below 1 for both riverine and oceanic discharge scenarios.

Zinc (II) Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.02	0.18	0.127
Q - Ocean:	0.002	0.18	0.013

Zinc (II) attributable to use of the notified chemical is expected to have low exposure to the aquatic compartment due to its efficient removal to biosolids in STPs. The risk quotient (PEC/PNEC) is below 1 for both riverine and oceanic discharge scenarios.

It is noted that zinc is ubiquitous in the environment and that the notified chemical represents just one of many anthropogenic sources. The majority of zinc (II) from the notified chemical is expected to be released to the terrestrial environment. Different environmental factors and characteristics of soils, such as pH, can result in changes to the mobility and bioavailability of zinc in soils over time. A PNEC for the terrestrial compartment, and therefore Q, have not been derived in this assessment. However, the contribution of the notified chemical as an anthropogenic source of zinc, at the proposed import volume and use pattern, is compared to Australian water and soil quality guideline limits.

In Australia, the ANZECC (2000) guideline limits for zinc in surface waters for ecosystem protection are 8

µg/L in freshwater and 15 µg/L in marine: both these trigger values apply at a hardness of 30 mg $CaCO_3$/L. Background zinc concentrations in Australian surface waters have been reported as <0.022-0.1 µg/L in marine waters, 0.39-3.8 µg/L in estuarine waters and 0.9 µg/L in fresh water (ANZECC, 2000). The PEC for zinc in freshwater surface waters (0.02 µg/L) represents a potential increase of 2.2% in zinc concentration in freshwater (river) compared to background levels, and accounts for 0.25% of the trigger value for ecosystem protection in freshwater, due to the use of the notified chemical. However, the PEC represents a worst-case calculation using a removal efficiency of 90% in STPs, whereas removal efficiency could be expected to exceed 99%.

In Australia, the guideline limits for the maximum allowable concentrations of zinc as a contaminant in biosolids with unrestricted use is 200 mg/kg dry solids based on ecological protection (NRMMC, 2004). At the proposed import volume and use pattern, the concentration of zinc in biosolids attributable to the notified chemical is calculated as 2.055 mg/kg (dry wt). The notified chemical is therefore expected to account for approximately 1% of the maximum allowable concentration for zinc in biosolids.

In Australia, the soil contaminant ceiling limit concentration for zinc is also 200 mg/kg dry solids (NRMMC, 2004). Background zinc concentrations in Australian soils range 1-263 mg/kg, with a calculated median background zinc concentration in soil of 39 mg/kg (NRMMC, 2004). At the proposed import volume and use pattern, the notified chemical may lead to a 0.14 mg/kg increase in zinc concentrations in agricultural soils over a 10 year period due to the application of biosolids. This represents a 0.36% increase with respect to the median background concentration over 10 years and accounts for 0.07% of the soil contaminant ceiling limit concentration for zinc.

The Australian and New Zealand Guidelines for Fresh and Marine Water Quality (ANZECC, 2000) contains the following trigger values for zinc in irrigation water: short-term (20 years) 5.0 mg/L; long-term (100 years) 2.0 mg/L; and, cumulative contamination loading limit 300 kg/ha. At the proposed import volume and use pattern, the concentration of zinc in effluent attributable to the notified chemical is calculated to be 0.023 µg/L. This accounts for <<0.01% of the short-term and long-term trigger value concentrations for zinc in irrigation waters.

The contribution of the notified chemical as an anthropogenic source of zinc is not expected to result in a significant increase to the concentration of zinc in surface waters or soils with respect to Australian environmental trigger values.

Therefore, on the basis of the PEC/PNEC ratio for the aquatic compartment, comparison with Australian soil and water quality guideline limits and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility ~50 g/L at 20 ºC

Method In house
Remarks Solubility of zinc L-lactate was determined between 10 and 85 ºC at 5 ºC intervals. Solutions contained sufficient substance to ensure saturation (indicated by the presence of precipitates) and were stirred for 2-4 hours until equilibrium was reached. Conductivity was measured and solubility determined by conductivity-solubility calibration curve. Results ranged from 4.22% at 10 ºC to 12.16% at 80 ºC. The pH was not reported.

The approximate value for solubility for the notified chemical of 50 g/L at 20 ºC was obtained from reading a graph of the above results, as provided by the notifier.
Test Facility Cao et. al. (2001)

Partition Coefficient (n-octanol/water) Lactic acid: log Pow = -0.62.at 20 ºC

Method OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks Test substance: lactic acid. Conducted in compliance with GLP standards and principles. Further details not available.
Test Facility US EPA (2002)

Dissociation Constant $K_1 = 0.006$
$K_2 = 0.03$

Method Details not available
Remarks Results were quoted by the notifier from a published paper. Zinc lactate shows two stages of dissociation.
Test Facility Davies & Monk (1954)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: Similar to OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain: Rat/Wistar Crl:(WI) WU BR

Vehicle: Water

Remarks - Method: The test substance at 2000 mg/kg bw was initially administered to 2 male rats, then on a separate day administered at the same dosage level to a further 3 males and 5 females.

As mortalities were observed at the 2000 mg/kg bw dosage level, 5 males and 5 females were treated with the test substance at 500 mg/kg bw.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5M/5F	500	0/10
II	5M/5F	2000	8/10

LD50: Between 500 and 2000 mg/kg bw

Signs of Toxicity: In group I (500 mg/kg bw), sluggishness, blepharospasm, piloerection, soiled fur and diarrhoea were noted in some or all of the animals within the first 24 hours following treatment.

In group II (2000 mg/kg bw), the two initially treated males survived, whereas the subsequently treated males and females died within 3 days post-treatment. Clinical signs noted in some or all of these animals included sluggishness, blepharospasm, piloerection, soiled fur, diarrhoea and an encrustation nose.

Effects in Organs: No effects were noted for group I. The animals in group II (2000 mg/kg bw) that were found dead during the study were not examined due to autolysis. In the surviving males, adherence of the liver to the stomach and intestines was noted at necropsy.

CONCLUSION: The notified chemical is harmful via the oral route.

TEST FACILITY: TNO (1996)

B.2. Irritation – skin

TEST SUBSTANCE: Notified chemical

METHOD: Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain: Rabbit/New Zealand White

Number of Animals: 6

Vehicle: None

Observation Period: 72 hours

Type of Dressing: Semi-occlusive.

Remarks - Method: Non-GLP study.

0.5 g of the notified chemical was applied to normal and abraded sites on the backs of the rabbits. The treated sites were covered with gauze patches humidified with water. After 24 hours, the patches were removed and remaining substance removed with distilled water or 5% sodium lauryl sulphate/water. Observations were recorded on patch removal and

48 hours post-patch removal.

RESULTS

Remarks - Results: Sligth erythema was noted in a single animal only at the non-abraded site on patch removal.

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

TEST FACILITY: Cosmepar (1994)

B.3. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3
- Observation Period: 72 hours
- Remarks - Method: No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2.7	2.7	2.7	3	72 hours**	3
Conjunctiva: chemosis	3.0	3.0	3.0	3	72 hours**	3
Conjunctiva: discharge	3.0	3.0	3.0	3	72 hours**	3
Corneal opacity	2.0	2.0	2.0	2	72 hours**	2
Iridial inflammation	1.0	1.0	1.0	1	72 hours**	1

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

Remarks - Results: At the 1, 24, 48 and 72 hour observations, effects were observed. The severity of the reactions tended to increase over the observation period and then remain constant over the final observations. Moderate corneal opacity, slight iritis, moderate redness, ischemic necrosis, severe swelling of the conjunctivae and severe ocular discharge were noted.

Due to the severity of the effects observed, the animals were killed following the 72 hour observation.

CONCLUSION: The notified chemical is irritating to the eye.

TEST FACILITY: TNO (1996b)

B.4. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3
- Observation Period: 7 days
- Remarks - Method: 0.01 mL of the test substance was administered onto the cornea of the right eye. The left eye remained untreated and served as the control. Observations were made at 1, 24, 48, 72 hours and 7 days post-administration.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2.0	3.0	1.3	3	<7 days	0
Conjunctiva: chemosis	1.3	2.3	1.3	3	<7 days	0
Conjunctiva: discharge	0.3	1.3	0.3	2	<7 days	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	1	<24 hours	0

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

Remarks - Results: No corneal effects were noted and only slight iridial effects were noted (1 animal) 1 hour post-administration. Conjunctival effects were noted up to and including the 72 hour observation, including moderate-severe redness and swelling of the conjunctivae, ischemic necrosis, and slight-moderate ocular discharge. The eye irritation effects had cleared within 7 days of administration.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: TNO (1997a)

B.5. Irritation – eye: Isolated Chicken Eye Test

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 438 Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants.

Number of corneas treated: 3

Remarks - Method: A concurrent positive control study was not conducted.

RESULTS

Conc. (%)	Swelling (%)	Max mean scores Opacity	Fluorescein	Irritation Category
100	1	0.5	0.2	I; I; I (Not irritating)

Remarks - Results: Slight corneal opacity was observed in all three eyes and very slight fluorescein retention was observed in one eye.

CONCLUSION: The notified chemical is not severely irritating to the eye.

TEST FACILITY: TNO (1996c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Biochemical/chemical oxygen demand (BOD/COD)

TEST SUBSTANCE	L (+) Lactic acid
METHOD	NEN 6634 Water-determination of Biological Oxygen Demand after n days (BODn). NEN 6633 Water-determination of Chemical Oxygen Demand (COD).
Inoculum	Activated sludge, domestic
Exposure Period	20 days
Auxiliary Solvent	None
Analytical Monitoring	BOD and COD
Remarks – Method	The above methods are stated to be similar to those in EC Test Guidelines C.8 and C.9. Tested at two concentrations, 2 and 4 mg/L.

RESULTS

Day	*BOD mg O_2/mg*	*COD mg O_2/mg*	*BOD/COD*
5	0.45	0.902	50%
20	0.60		67%

Remarks – Results	The control substance glucose and glutamic acid had a BOD5 slightly below the validity criteria. The microbial activity of the inoculum was considered sufficient for the purpose of the test.
CONCLUSION	Lactic acid is readily biodegradable.
TEST FACILITY	TNO (1993)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Semi-static.
Species	*Brachydanio rerio*
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	214 mg $CaCO_3$/L
Analytical Monitoring	ICP-AES (zinc)
Remarks – Method	The test was conducted in accordance with the above guidelines and in compliance with GLP standards and principles. There were no significant deviations from the protocol.

RESULTS

Nominal concentration of n.c. mg/L	*Number of Fish*	*Mortality*				
		3 h	*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0	0
10	10	0	0	0	0	0
18	10	0	0	0	0	0
32	10	0	0	0	0	0
56	10	0	0	0	0	0
100	10	0	0	1	1	1
180	10	0	10	10	10	10
320	10	0	10	10	10	10

n.c. = notified chemical

LC50 (nominal concentration of n.c.)	134 mg/L at 24 hours (100-180 mg/L). 100 mg/L at 48 hours. (100-145 mg/L) 100 mg/L at 72 hours. (100-145 mg/L) 100 mg/L at 96 hours. (100-145 mg/L)
LC50 (measured as Zn)	19.6 mg Zn/L at 96 hours
LC50 (n.c. based on measured Zn)	73 mg n.c./L at 96 hours
NOEC (nominal concentration of n.c.)	56 mg/L at 96 hours (mortality). 100 mg/L at 96 hours (condition).
NOEC (measured as Zn)	10.7 mg Zn/L at 96 hours (mortality). 19.6 mg Zn/L at 96 hours (condition).
Remarks – Results	After 24 hours the actual concentration of soluble zinc ranged 44-69%: results were reported in both nominal concentration of the notified chemical and measured zinc concentration. Despite a reported solubility of 5 g/100mL for the notified chemical, turbidity was observed in the test solutions with a concentration of 32 mg/L and more. The slope of the concentration effect curve was too steep to be calculated. Since the measured concentration varied from the nominal by more than 20%, the endpoint of the notified chemical is based on the measured zinc concentration.

CONCLUSION The notified chemical is harmful to fish.

TEST FACILITY TNO (1996d)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 *Daphnia sp*. Acute Immobilisation Test – Static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	203 mg $CaCO_3$/L
Analytical Monitoring	ICP-AES (zinc)
Remarks – Method	The test was conducted in accordance with the above guidelines and in compliance with GLP standards and principles. There were no significant deviations from the protocol.

RESULTS

Concentration of n.c.			*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual (%)*			*24 h*	*48 h*
(mg/L)	*T=0 h*	*T=48 h*			
Control			20	0	0
1.0	87	78	20	0	0
1.8			20	0	0
3.2	85	106	20	0	0
5.6			20	0	8
10	87	91	20	4	12
18			20	10	16
32	79	47	20	10	19
56			20	12	20
100	79	44	20	17	20

n.c. = notified chemical

EC50 (nominal concentration of n.c.)	31 mg /L at 24 hours (24-40 mg/L) 8.9 mg /L at 48 hours (6.9-11 mg/L)
EC50 (measured as Zn)	1.7 mg Zn/L at 48 hours
EC50 (n.c. based on measured Zn)	6.3 mg n.c./L at 48 hours
NOEC (nominal concentration of n.c.)	3.2 mg/L at 48 hours (mobility) 1.8 mg/L at 48 hours (condition)
NOEC (measured as Zn)	0.59 mg Zn/L at 48 hours (mobility) 0.33 mg Zn/L at 48 hours (condition)
Remarks - Results	After 48 hours the actual concentration of soluble zinc ranged 56-125%: results were reported as both nominal concentration of the notified chemical and measured zinc concentration. After 24 and 48 h the test solutions of 56 and 100 mg/L were slightly turbid with some undissolved material on the surface of the test solution. Undissolved material was observed on the bottom of the test vessel of the 100 mg/L solution. The average measured concentration varied from the nominal concentration by more than 20%. The notified chemical endpoint is based on the measured concentration of Zn.

CONCLUSION The notified chemical is toxic to aquatic invertebrates.

TEST FACILITY TNO (1992)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	$Nominal_{low\ hardness}$: 0, 32, 64, 130, 260, 520, 1040 µg/L $Nominal_{high\ hardness}$: 0, 64, 130, 260, 520, 1040, 2100 µg/L
Auxiliary Solvent	None
Water Hardness	Low hardness medium: 15.3 mg $CaCO_3$/L High hardness medium: 146.3 mg $CaCO_3$/L
Analytical Monitoring	AAS
Remarks - Method	After a range finding test a definitive test was conducted in accordance with the guideline above and in compliance with GLP standards and principles. There were no significant deviations to the protocol.

RESULTS

	Biomass	*Growth*		
	E_bC50 *(µg n.c./L at 72 h)*	*E_rC50* *(as µg n.c./L at 72 h)*	*(as µg Zn/L)*	*NOEC* *(µg n.c./L)*
Low hardness medium	270 (95% CI: 260-520)	520 (95% CI: 440-600)	127	32
High hardness medium	800 (95% CI: 520-1000)	2100 (95% CI: 1800-2500)	515	<64

n.c.= notified chemical

Remarks - Results

The validity criteria were met. Effects values were calculated using a Kooijman parametric model. The concentration of the notified chemical varied between 82 and 94% of the nominal, therefore, analysis of the results are based on nominal values.

The results indicate that toxicity of the notified chemical is mitigated somewhat in high hardness water. However, the notified chemical endpoint is based on the low hardness medium results. This is considered appropriate to apply to Australian conditions on the basis of the water hardness of 30 mg $CaCO_3$/L that applies to the ANZECC (2000) trigger values for zinc.

The values for effects based on zinc (i.e. E_rC50 as µg Zn/L) are stated to be comparable or higher than values cited in the literature. The report concludes that the inhibiting effects can best be ascribed to the zinc content of the notified chemical.

CONCLUSION

The notified chemical is very toxic to algae.

TEST FACILITY

TNO (1997b)

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