File No: STD/1564

March 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Manganese, acetate 2-ethylhexanoate octahydro-1,4,7-trimethyl-1*H*-1,4,7-triazonine complexes

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

This Public Report is 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/1564	Huntsman Pigments and Trading Pty Ltd	Manganese, acetate 2-ethylhexanoate octahydro-1,4,7-trimethyl-1*H*-1,4,7-triazonine complexes	ND*	≤ 10 tonne/s per annum	Component of paints and coatings

* Not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

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

Hazard classification	*Hazard statement*
Acute (Category 3)	H402 – Harmful to aquatic life
Chronic (Category 3)	H412 – Harmful 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 the proposed manner, 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 and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

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.
- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (Safe Work Australia, 2015) or relevant State or Territory Code of Practice.
- 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 of Classification and Labelling of Chemicals (GHS)*

as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

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

Emergency procedures

- Spills or accidental release of the notified 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 concentration of the chemical in the end-use paint and coating products exceeds 0.1%;
- additional information has become available to the person as to the repeated dose toxicity and/or reproductive/developmental toxicity of the chemical via the inhalation route.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from component of paints and coatings, 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.

(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)
Huntsman Pigments and Trading Pty Ltd (ABN: 45 004 275 941)
21 David Street
DANDENONG VIC 3175

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
European Chemicals Agency (ECHA) (2012)

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Manganese, acetate 2-ethylhexanoate octahydro-1,4,7-trimethyl-1*H*-1,4,7-triazonine complexes

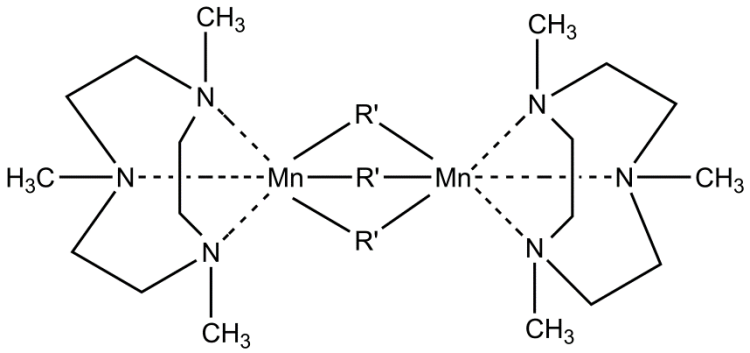
MARKETING NAME(S)
Nuodex DryCoat

OTHER NAME(S)
DryCoat-Manganese Complex

CAS NUMBER
1381939-25-8

MOLECULAR FORMULA
$C_{42}H_{87}Mn_2N_6O_6$ and $C_{36}H_{75}Mn_2N_6O_6$

STRUCTURAL FORMULA



R' = $CH_3(CH_2)_3CH(C_2H_5)CO_2$- / CH_3CO_2-

MOLECULAR WEIGHT
629–882 Da

ANALYTICAL DATA
Reference single crystal and powder X-ray diffraction, ^{1}H NMR, mass spectroscopy, ATR-IR, HPLC-UV and ICP spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
95–100%

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)

Chemical Name di-μ-(acetato-*O*)-μ-(2-ethylhexanoato-O)-bis(*N*,*N*',*N*''-trimethyl-1,4,7-triazacyclononane-*N*,*N*',*N*'')dimanganese
CAS No. *Weight %* ≤ 3

Chemical Name tri-μ-(acetato-*O*)-bis(*N*,*N*',*N*''-trimethyl-1,4,7-triazacyclononane-*N*,*N*',*N*'')dimanganese
CAS No. *Weight %* < 0.05

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: sticky white solid

Property	Value	Data Source/Justification
Melting Point	203 °C	Measured
Boiling Point	Not determined	Melting point is > 200 °C.
Density	1,140 kg/m^3 at 21.5 °C	Measured
Vapour Pressure	Not determined	Could not be determined because appropriate thermodynamic properties are unknown.
Water Solubility	For manganese: 7.29×10^{-2} g/L (loading rate of 1 g/L) 0.706 g/L (loading rate of 10 g/L) 1.73 g/L (loading rate of 100 g/L)	Measured, solubility is loading rate dependent.
Hydrolysis as a Function of pH	Not determined	The notified chemical does not contain readily hydrolysable functionalities under normal environmental conditions of pH 4–9.
Partition Coefficient (n-octanol/water)	Not determined	The notified chemical may partition to n-octanol at high concentration based on a preliminary test. The test method is not applicable at low concentrations due to the chemical being in suspension.
Adsorption/Desorption	Not determined	The notified chemical is expected to sorb on soil/sediment based on its potential to ionise.
Dissociation Constant	Not determined	The notified chemical contains ionisable functionalities. Therefore, the notified chemical has potential to be ionised under normal environmental conditions (pH 4–9).
Particle Size	Not determined	Substance is a sticky solid.
Surface Tension	64.1 mN/m	Not surface active at 1.1 g/L loading rate
Flash Point	Not determined	Substance is a solid with a melting point > 200 °C.
Flammability	Combustion failed to propagate	Measured (EU method A.10)
Autoignition Temperature	Not auto flammable up to its melting point	Measured (EU method A.16)
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

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. The notified chemical is subject to reaction with strong oxidising compounds.

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 of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as part of a formulation.

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

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

PORT OF ENTRY
The exact port of entry for the notified chemical is undetermined.

IDENTITY OF MANUFACTURER/RECIPIENTS
Manufacturer: Huntsman Pigments UK Ltd. The notified chemical will be received in Australia by the notifier for distribution to paint companies and importers of the product for use in their own paint products or as a component of mixtures to be used in downstream inks, resin, paint and coating formulations.

TRANSPORTATION AND PACKAGING
Products containing the notified chemical will be transported (primarily by road) in metal drums, intermediate bulk containers (IBCs) or in (paint) containers as a formulation with paint.

USE
The notified chemical will be used as a primary drier and imported as a formulated product (at < 10% concentration) and also in end-use paint and coating products (at < 0.1% concentration). The notified chemical will be used in coating applications, including: paints, inks and unsaturated polyester resins. End-use products containing the notified chemical will be used by workers and the public.

OPERATION DESCRIPTION
Reformulation
The notified chemical will be imported for reformulation in Australia. At the reformulation sites, the notified chemical will be blended into end-use industrial and commercial products, mainly through automated processes. The notified chemical will be pumped directly from the drum or IBC via a fixed or flexible pipeline directly into the end-use cans with the paint/coating product and then sealed.

End use
Finished ink, resin, paint and coating products containing the notified chemical (at < 0.1% concentration) may be used by consumers or professionals. The end-use products may be applied to surfaces by spray, brush or roller.

Where the notified chemical is imported in finished paint and coating products, the will be stored at the notifier's warehouse before being distributed to warehouses and shops for retail sale to consumers.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Industrial worker	0.5	< 150
Professional paint/coatings workers	7	240

EXPOSURE DETAILS

Transport and Storage
Transport and storage workers may come into contact with the imported product containing the notified chemical (at < 10% concentration), only in the unlikely event of an accident. The notified chemical should be handled with good working practices, gloves, eye protection and suitable work clothing should be worn. If contact with the material occurs then clothes should be changed and skin washed immediately.

Reformulation
During the paint formulation processes, dermal and ocular exposure to the notified chemical (at < 10% concentration) may occur. Exposure is expected to be minimised through the use of personal protective equipment (PPE), including eye protection, impervious gloves and appropriate industrial clothing. Due to the nature of the processes and the expected low volatility of the notified chemical, inhalation exposure during reformulation is not anticipated.

End use
At end-use sites, dermal, ocular and/or inhalation exposure to the paint containing the notified chemical (at < 0.1% concentration) may occur during transfer, application and cleaning processes. The potential for exposure is expected to be minimised through the use of PPE (goggles, impervious gloves, coveralls) by workers and use of respiratory protection during spray applications. Once the coating is dried, the notified chemical will be bound within the paint/coating matrix and will not be available for exposure.

6.1.2. Public Exposure
Imported products containing the notified chemical at 10% concentration will be available only for industrial use and will not be sold to the public. Further reformulation processes will result in the notified chemical concentration being < 0.1% in final coating applications, that may be sold into consumer applications to the general public in the form of formulated paint. The public may be exposed (dermal, ocular or inhalation) to the notified chemical during use of the formulated paints/coatings containing it at < 0.1% concentration.

Post application, the notified chemical is not consumed or released but will be bound within the matrix of the paint/coating at low concentrations (< 0.1% in final coating applications) and as such will not be readily available for significant exposure to humans via the service life of the coated article under normal handling and use.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical 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 > 2,000 mg/kg bw; low toxicity
Skin irritation (in vitro reconstructed human epidermis model)	non-corrosive
Skin irritation (in vitro reconstructed human epidermis model)	non-irritating
Eye irritation (in vitro)	non-irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, combined oral (gavage) repeat dose with reproductive/developmental screening toxicity – 43 days.	NOAEL = 150 mg/kg bw/day (systemic)

	NOEL = 150 mg/kg bw/day (reproductive and developmental)
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro (mammalian chromosome aberration test)	genotoxic
Genotoxicity – in vivo (mammalian erythrocyte micronucleus test)	non genotoxic

Toxicokinetics, metabolism and distribution.
No data are available. Based on the the limited solubility at low loadings and the molecular weight (> 500 Da), the notified chemical is not expected to be significantly absorbed across the skin.

Acute toxicity.
The notified chemical was found to have low acute oral toxicity in rats. Acute inhalation and dermal toxicity studies were not performed on the grounds of animal welfare, low concentration of use in products, and physicochemical properties which suggest a low potential for a significant rate of absorption of the notified chemical through the skin. The potential for absorption of the notified chemical by the inhalation route is uncertain.

Irritation and sensitisation.
In vitro skin corrosion and irritation studies were conducted. The notified chemical was found to be non-corrosive and non-irritating to the skin based on the in vitro studies.

An in vitro eye irritation study, using the reconstructed human cornea model, found the notified chemical not to be an eye irritant.

The notified chemical was not a skin sensitiser in a local lymph node assay (LLNA) in mice, with reported stimulation indices of 1.28, 1.55 and 2.30 at 5, 10, and 25% concentration, respectively. No signs of local skin irritation or irritation indicated by an increase in ear thickness was observed in the preliminary screening test.

Repeated dose toxicity.
No data were available for the repeated dose toxicity of the notified chemical via the inhalation route. An oral (gavage) combine repeated dose toxicity with reproductive/developmental screening test on the notified chemical was conducted with rats, in which the test substance was administered at 30, 150 and 300 mg/kg bw/day) for at least 43 consecutive days.

There were four unscheduled deaths around the time of parturition in the high dose group which, in addition to litter losses post partum, increases the uncertainty for the assessment of litter responses at the high dose due to the relatively low number of litter (five) available for assessment. There were no toxicologically significant changes noted in mating, fertility and gestational parameters. Excluding the clinical observations for decendent females, the incidence and distribution of the other clinical observations for surviving animals did not indicate substance related effects at any dose.

There were no clear dose-response relationships observed for any of the effects reported in the high dose group. The No Observed Adverse Effect Level (NOAEL) for systemic toxicity and the No Observed Effect Level (NOEL) for reproductive and developmental toxicity was established as 150 mg/kg bw/day for this study.

A component of the notified chemical, 2-ethylhexanoic acid, is classified Reproductive and Developmental Toxicity (Category 2) under the GHS (NICNAS). The notified chemical is less soluble than the related chemical 2-ethylhexanoic acid, manganese salt (1.784 g/L Mn at a loading of 50 g/L) (REACH), which is classified Reproductive and Developmental Toxicity (Category 2) and Single Target Organ Toxicity – Repeated exposure (Category 2) (via inhalation). The notified chemical will be present in products at a maximum concentration of 10%, equivalent to a loading of 10 g/L. The solubility of notified chemical (0.706 g/L Mn) corresponds to a maximum potential free concentration of 2-ethylhexanoic acid of 2.78% which is below the cutoff concentration for classification of 2-ethylhexanoic acid (< 5%) (Safe Work Australia).

Mutagenicity/Genotoxicity.
The notified chemical was not mutagenic in a bacterial reverse mutation study and was clastogenic in an *in vitro* mammalian chromosome aberration test. The notified chemical was not genotoxic in an *in vivo* mammalian erythrocyte micronucleus test.

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the available information, the notified chemical is expected to be of low hazard. Limited dermal absorption of the notified chemical is expected.

Ocular, inhalation and dermal exposure of workers to the notified chemical at concentrations up to 10% may occur during reformulation operations and at concentration of up to 0.1% when applying the paint/coating by brush, roller or spray. These exposures are expected to be lowered by the use of engineering controls and personal protective equipment. As such, the risk to workers from exposure to the notified chemical is not considered to be unreasonable.

6.3.2. Public Health
There is the potential for direct dermal, ocular and inhalation exposure of the public to the notified chemical at up to 0.1% when coatings (DIY use) are applied by using brush, roller or spray. The effects of the notified chemical following inhalation exposure are unknown, and the public may not use PPE when spraying products containing the notified chemical. However, the frequency and extent of exposure is expected to be less than that of professional painters.

The public may come into contact with surfaces that have been coated with coatings containing the notified chemical; however, once cured, the notified chemical will not be bioavailable.

Therefore, when used in the proposed manner, the risk to public health from exposure to the notified chemical is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported into Australia and will be reformulated into products including paints/coatings, inks and unsaturated polyester resins. The notified chemical will be pumped directly from the drum into the end-use containers via a fixed or flexible pipeline directly and then sealed. A significant release of the notified chemical is not expected during these activities. Environmental release of the notified chemical is unlikely during importation, storage and transportation.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be reformulated into a variety of products including paints/coatings, inks and unsaturated polyester resins. Therefore, release of products containing the notified chemical to the environment is not expected under normal conditions.

Paints/coatings
The notified chemical will be used as a component of paints/coatings. The major release of the notified chemical to the aquatic environment may come from the cleaning of application equipment, especially the brushes or rollers used by do-it-yourself (DIY) users. It is expected that up to 5% of the imported quantity of notified chemical may be disposed of to sewers during the clean-up of paint application equipment. Notified chemical released to sewers is expected to be treated at the wastewater treatment facility during the waste water treatment processes. The residual paint remaining in empty containers is expected to be disposed of to landfill with the discarded containers.

Ink
Releases of ink containing the notified chemical to the environment are not expected under normal conditions. However, if leakage or spillage does occur, the ink will be contained with absorbent material, which is expected to be disposed of to landfill along with the containers.

RELEASE OF CHEMICAL FROM DISPOSAL

Paints/coatings
The residual paints/coatings, containing the notified chemical, remaining in empty containers is expected to be disposed of to landfill with the discarded containers. The disposal of the major fraction of the notified chemical will be linked to the ultimate disposal of the dried paint/coating on painted/coated articles. It is expected that the majority of the notified chemical will ultimately be disposed of to landfill in the form of discarded paint chips or as coated articles.

Ink
The majority of the ink will be bound to printed paper that will be disposed of to landfill or recycled. Half of the paper that the notified chemical is bound to is expected to be recycled, which may result in the release of a proportion of the notified chemical to the aquatic compartment. Waste paper is pulped using a variety of chemical treatments that result in fibre separation and ink detachment from the fibres. The effluent is expected to be released to sewer.

7.1.2. Environmental Fate
The notified chemical is not readily biodegradable based on the provided study. However, the notified chemical showed 46% biodegradation over the 28 days. For the details of the biodegradability study please refer to Appendix C.

Paints/coatings
The majority of the notified chemical is expected to be sent to landfill with the associated articles. In landfill, the notified chemical is not expected to leach due to the expected adsorption to soil due to its potential to ionise under normal environmental conditions.

The notified chemical, which may be released to the sewer from DIY uses, is expected to adsorb to sludge in sewage treatment plants (STPs) due to its tendency to sorb to soil/sludge sediment. The sludge containing notified chemical may be sent to landfill or applied to soils for land remediation. Notified chemical released to surface waters is expected to sorb to suspended solids and suspended sediments in water. Due to its potential to ionise under normal environmental conditions, the notified chemical is unlikely to cross the lipid cell membrane and therefore, is not expected to bioaccumulate. Ultimately, the notified chemical is expected to eventually degrade via biotic and abiotic processes in landfill or aquatic environment, or by thermal decomposition during the metal reclamation processes, to form water vapour, inorganic salts and oxides of carbon and nitrogen.

Ink
The majority of the notified chemical, from the use of ink, is expected to enter the environment from disposal of printed paper products that ink containing the notified chemical will be used on. Approximately 50% of the notified chemical will be disposed of to landfill by binding on the printed waste paper. Notified chemical that is not bound to paper in landfill may not significantly leach due to its ionisation potential. The remaining 50% of the notified chemical has the potential to be released to sewer, after the de-inking of paper during recycling. Some of the notified chemical is expected to be removed from the sewage during sewage treatment processes by sorption to sludge. However, some of the notified chemical from paper recycling may still be released from STPs into surface waters. Notified chemical that enters surface waters from landfill leachate and STPs is expected to disperse and eventually degrade. The notified chemical is expected to biodegrade in the environment based on its biodegradation study. The notified chemical is not expected to bioaccumulate due to its potential cationicity. The notified chemical is expected to eventually degrade *in-situ* by abiotic and biotic processes into water vapour, inorganic salts and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)
The notified chemical will be reformulated into products including coatings, paints, inks and unsaturated polyester resins. It is expected that up to 5% of the imported quantity of notified chemical may be disposed of to sewers during the clean-up of paint application equipment. It is assumed that 50% of the paper products containing the notified chemical will be recycled and released into sewers, with no removal of the notified chemical during recycling or STP processes. As the notified chemical is to be processed at paper recycling

facilities located throughout Australia, it is anticipated that such releases will occur on 365 days into the Australian effluent volume. The resultant estimate for the predicted environmental concentration (PEC) in sewage effluent nationwide is presented below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	1.370	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.324	µg/L
PEC - Ocean:	0.0324	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.324 µg/L may potentially result in a soil concentration of approximately 2.16 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 10.8 µg/kg and 21.6 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 > 100 mg/L	Not harmful to fish
Daphnia Toxicity	EC50 = 83 mg/L	Harmful to aquatic invertebrates
Algal Toxicity	EC50 = 51 mg/L	Harmful to algae
Inhibition of Bacterial Respiration	EC50 > 1,000 mg/L	No inhibitory effect to the sludge bacteria respiration

The notified chemical is not harmful to fish but it is harmful to aquatic invertebrates and algae based on the acute toxicity. Therefore, under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS; United Nations, 2009), the notified chemical is formally classified as Acute Category 3; Harmful to aquatic life. Based on the acute toxicity and lack of ready biodegradability of the notified chemical, it has been formally classified under the GHS as Chronic Category 3; Harmful to aquatic life with long lasting effects.

7.2.1. Predicted No-Effect Concentration

The endpoint for the most sensitive species (Algae) is used to calculate the predicted no-effect concentration (PNEC). An assessment factor of 100 was used as the endpoint for the most sensitive species is conservatively estimated.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Algae)	51	mg/L
Assessment Factor	100	
PNEC:	510	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:	0.324	510	0.0006
Q - Ocean:	0.0324	510	0.00006

The Risk Quotients (Q = PEC/PNEC) for the worst case discharge scenario have been calculated to be much less than 1 for the river and ocean compartments. This indicates that the notified chemical is expected to be present in the aquatic environment at much lower concentrations than the concentration expected to cause adverse effects to aquatic organisms. The notified chemical is biodegradable and is not expected to be bioaccumulative. Therefore, the notified chemical is not expected to pose an unreasonable risk to the aquatic environment based on its reported use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility The water solubility results for manganese are 7.29×10^{-2} g/L at a loading rate of 1 g/L, 0.706 g/L at a loading rate of 10 g/L and 1.73 g/L at a loading rate of 100 g/L

Method OECD TG 105 Water Solubility.
EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Flask Method. The standard and sample solutions were analysed for manganese (mass = 55) using an ICP-MS. Whereas, the total Organic Carbon (TOC) concentration calculated using a TOC analyzer.

Nominal Loading Rate (g/L)	Concentration (g/L)	
	TOC	Manganese
1	0.51	7.29×10^{-2}
10	5.59	0.706
100	7.16	1.73

Test Facility Harlan (2012a)

Melting Point 203 °C

Method Capillary Method (no details provided)
Remarks Melting point determined using Stuart Analogue SMP11 – Capillary Method
Test Facility Rockwood Pigments (2012)

Density 1,140 kg/m^3 at 21.5 °C

Method OECD TG 109 Density of Liquids and Solids.
EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks Gas comparison pycnometer. Gas: Helium
Test Facility Harlan (2012a)

Flammability

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks Determined by measuring burning rate of notified chemical. Combustion failed to propagate
Test Facility Harlan (2012e)

Autoignition Temperature

Method EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks Determined by heating the notified chemical in an oven and observing any ignition. The notified chemical was determined not to have a relative self-ignition temperature below its melting temperature.
Test Facility Harlan (2012e)

Oxidising Properties

Method EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids).
Remarks Examination of the notified chemical to react exothermically with a combustable material. The notified chemical was was determined not to have oxidising properties.
Test Facility Harlan (2012e)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Procedure. EC Council Regulation No 440/2008 B.1 bis Acute toxicity (oral) fixed dose method.
Species/Strain	Rat/Wistar (RccHan™:WIST)
Vehicle	Arachis oil BP
Remarks - Method	Exception to GLP standards – No analysis was conducted to determine the homogeneity concentration or stability of the notified chemical formulation. A sighting study was conducted with 1 female animal (300 mg/kg bw) to determine the dose level for the main study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	1	300	0/1
2	1	2,000	0/1
3	4	2,000	0/4

Group 1	
LD50	300 mg/kg bw
Signs of Toxicity	Signs of systemic toxicity noted during day of dosing were hunched posture and pilo-erection. The animal appeared normal one day after dosing.
Effects in Organs	No abnormalities detected
Remarks - Results	Animal recorded expected body weight gain over the study period.
Group 2 & 3	
LD50	2,000 mg/kg bw
Signs of Toxicity	No signs of toxicity noted
Effects in Organs	No abnormalities detected
Remarks - Results	Animals recorded expected body weight gain over the study period.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Harlan (2012f)

B.2. Irritation – skin (in vitro)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 431 In vitro Skin Corrosion - Human Reconstructed Human *Epidermis* Test Method EC Council Regulation No 440/2008 B.40 BIS. In vitro Skin Corrosion - Human Skin Model Test
Vehicle	N/A, notified chemical applied topically as a white solid and 0.9% w/v sodium chloride added for wetting of test item.
Remarks - Method	Glacial acetic acid used as positive control, 0.9% w/v sodium chloride as negative control. Testing not performed in triplicate (duplicate only).

RESULTS

Test material	*Mean OD_{540} of duplicate tissues*	*Relative mean Viability (%)*
Negative control 240 minutes	0.260	100
Test substance 3 minutes	0.221	85

Test substance 60 minutes	0.161	61.9
Test substance 240 minutes	0.209	80.4
Positive control 240 minutes	0.015	5.8

OD = optical density

Remarks - Results: Only averaged numbers provided. SD cannot be determined.

CONCLUSION: The notified chemical was non-corrosive to the skin under the conditions of the test.

TEST FACILITY: Harlan (2012g)

B.3. Irritation – skin (in vitro)

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 439 In vitro Skin Irritation: Reconstructed Human *Epidermis* Test Method
Method B46 of Commission Regulation (EC) No. 440/2008/EC

Vehicle: N/A, notified chemical applied topically as a white solid.

Remarks - Method: Dulbecco's Phosphate Buffered Saline with Ca^{++} and Mg^{++} was used as the negative control. Sodium Dodecyl Sulphate 5% w/v was the positive control. The Notified chemical did not directly reduce 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT).

RESULTS

Test material	*Mean OD_{540} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	0.738	100	3.1
Test substance	0.807	109.4	5.3
Positive control	0.072	9.8	1.8

OD = optical density; SD = standard deviation

Remarks - Results: The relative mean viability of the notified chemical treated tissues was 109.4% after a 15 minute exposure period compared to the negative control.

CONCLUSION: The notified chemical was non-irritating to the skin under the conditions of the test.

TEST FACILITY: Harlan (2012h)

B.4. Irritation – eye (in vitro)

TEST SUBSTANCE: Notified chemical

METHOD: Determination of Ocular Irritation Potential Using the SkinEthic Reconstituted Human Corneal Epithelium Model

Vehicle: N/A, notified chemical applied topically as a white solid.

Remarks - Method: A solution containg Na_2HPO_4 (0.142 g/L), Glucose (1.802 g/L), HEPES (7.149 g/L), KCl (0.224 g/L) and NaCl (7.597 g/L) was used as the negative control. Sodium Dodecyl Sulphate 2% w/v prepared in sterile distilled H_2O was the positive control. The Notified chemical did not directly reduce 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT).

RESULTS

Test material	*Mean OD_{540} of duplicate tissues*	*Relative mean viability (%)*

Negative control	0.900	100
Test substance	0.817	90.8
Positive control	0.196	21.8

OD = optical density

Remarks - Results: The notified chemical produced a result of 90.8% mean viability compared to the negative controls tisses, where the mean viability of the negative control is set at 100%.

CONCLUSION: The notified chemical was considered to be non-irritating to the eye under the conditions of the test.

TEST FACILITY: Harlan (2012i)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
B.42 Skin Sensitisation (Local Lymph Node Assay) of commission Regulation (EC) No. 440/2008

Species/Strain: Mouse / CBa/ca strain

Vehicle: Ethanol / Water (distilled) - 70:30 ratio

Preliminary study: Yes – Concentration of notified chemical at 25% w/w in ethanol/ distilled water (70:30 ratio). No changes in bodyweight and no mortality observed in treated animals. No signs of systemic toxicity, visual local skin irritation or irritation indicated by an ≥ 25% increase in mean ear thickness were noted.

Positive control: Not conducted in parallel with the notified chemical, but had been conducted previously in the test laboratory using a group of 5 animals treated with 50 µL (25 µL per ear) of a-Hexylcinnamaldehyde, tech., 85% as a solution in ethanol/distilled water at a ratio of 70:30 at a concentration of 15% v/v. A further control group of five animals was treated with ethanol/distilled water alone.

Remarks - Method: Exception to GLP standards – No analysis was conducted to determine the homogeneity concentration or stability of the notified chemical formulation. Stimulation index ≥ 3.0 indicates a positive result.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	5	905.06 ±151.44	N/A
5	5	1,159.33 ± 307.06	1.28
10	5	1,400.02 ± 538.84	1.55
25	5	2,082.68 ± 955.78	2.30
Positive Control			
15	5	*Data not provided*	6.16

EC3

Remarks - Results: There were no deaths and no signs of systemic tocxicity were noted in the test or control animals during the test. Bodyweight changes of the test animals between day 1 and day 6 were comparable to those observed in the corresponding control group animals over the same period.

CONCLUSION: There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY: Harlan (2012j)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	Rat/Wistar Han™:RccHan™:WIST
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 43 days (males), day 5 post partum (females) Dose regimen: 7 days per week
Vehicle	Arachis oil BP
Remarks - Method	

RESULTS

Group	*Number and Sex of Animals*		*Dose mg/kg bw/day*	*Mortality*
	Male	Female		
control	12	12	0	0/24
low dose	12	12	30	0/24
mid dose	12	12	150	0/24
high dose	12	12	300	4F/24

Mortality and Time to Death

There were four unscheduled deaths around the time of parturition in the high dose group during the study. One female was found dead after previously showing ptosis, piloerection, lethargy and hunched posture. The remaining three females were killed due to adverse clinical signs including ptosis, piloerection, hunched posture, decreased respiration rate and lethargy.

Clinical Observations

Both sexes in the high dose group had increased salivation post-dosing. One male in the mid-dose group showed increased salivation post-dosing on one occasion. No clinical signs were observed or toxicologically significant changes noted in behaviour, functional performance, sensory activity assessment, food efficiency or water consumption for animals of either sex, dosed at any level, throughout the study period.

In the high dose group, females showed lower body weight gain during the final week of gestation compared with controls. The body weight of dams on day 1 of lactation and body weight gain to day 4 was slightly lower than controls. In the high dose group, females showed reduced food consumption during lactation compared with controls. Excluding the clinical observations for decendent females, the incidence and distribution of the other clinical observations for surviving animals did not indicate substance related effects at any dose.

There were no toxicologically significant changes noted in mating performance, fertility and gestation lengths. In the high dose group four females died around the time of parturition and a further three litters showed total litter loss post partum.

In the high dose group there was no effect of treatment on corpora lutea and implantations counts. Although three litters showed total litter loss post partum, offspring losses were similar to control for litters successfully reared to Day 4. There was no effect of treatment on corpora lutea count, pre-implantation loss, implantations count, post-implantation loss, total litter size, post natal survival, litter size or sex ratio in the mid- and low-dose groups.

In the high dose group, offspring body weight and litter weight on Day 1 and subsequent body weight gain to Day 4 was slightly lower than control but there was no clear association with treatment. Offspring survival was low for some litters and these offspring showed the most clinical signs but these were typical for the age observed. Offspring necropsy revealed a higher incidence of no milk present in the stomach but no evidence of any morphological change for the offspring.

Laboratory Findings – Clinical Chemistry, Haematology

There were no toxicologically significant changes in haematology parameters. Females in the high dose group

showed statistically significant increases in mean glucose levels compared with controls.

Effects in Organs

Females in the high dose group had statistically significant increases in mean absolute and body weight-relative adrenal weights compared with controls.

In the high dose group there was ulceration, submucosal inflammation and epithelial hyperplasia of the stomach in 1 male; epithelial hyperplasia in 3 females; and one female ulceration of the stomach. Thymic atrophy was observed for 7 females. There were 4 decedent females and 3 total litter loss females showed decreased secretion of the mammary gland. Centrilobular necrosis of the liver was observed for 2 decedent females.

Remarks – Results

There were four unscheduled deaths around the time of parturition in the high dose group, and in addition to litter losses post partum, increases the uncertainty for the assessment of litter responses at the high dose due to the relatively low number of litter (five) available for assessment. There were no statistically significant effects observed that showed a clear dose-response relationship.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) for systemic toxicity and the NOEL for reproductive and developmentat toxicity was established as 150 mg/kg bw/day in this study, based on the adverse effects at the high dose level.

TEST FACILITY Harlan (2013a)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure and Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA, WP2uvrA (pKM101), WP2 (pKM101)
Metabolic Activation System	Rat liver homogenate/microsomal preperation, 10% liver in S9 in standard co-factors (S9-mix)
Concentration Range in Main Test	a) With metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate b) Without metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate
Vehicle	Dimethyl sulphoxide
Physical Form	Suspension
Remarks - Method	Notified chemical formed the best dosable suspension in dimethyl sullhoxide. Exception to GLP standards – No analysis was conducted to determine the homogeneity, concentration or stability of the notified chemical formulation. Prior to use, solvent was dried to remove water using molecular sieves.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000			negative
Test 2		> 5,000		negative
Present				
Test 1	> 5,000			negative
Test 2		> 5,000		negative

Remarks - Results No significant increases in the frequency of reverant clonies were recorded for any of the bacterial strainsm with any dose of the test item, either with or without metabolic activation or exposure method.

CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Harlan (2012k)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test.
Species/Strain	*Homo sapiens sapiens*
Cell Type/Cell Line	Lymphocytes
Metabolic Activation System	S9-mix
Vehicle	Acetone
Remarks - Method	Exception to GLP standards – No analysis was conducted to determine the homogeneity, concentration or stability of the notified chemical formulation. Prior to use, solvent was dried to remove water using molecular sieves. In the absence of S9, mitomycin C (MMC) was used at 0.4 µg/mL (dissolved in Minimal Essential Medium) in the main experiment. In the presence of S9, cyclophosphamide (CP) was used at 5 µg/mL (dissolved in dimethyl sulphoxide) in the main experiment.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	0.0, 9.77, 19.53, 39.06, 78.13, 156.25, 312.50, 625, 1250, 2500	4 hours	20 hours	24 hours
Test 2	0.0*, 20, 40, 80*, 160*, 320*, 480*, 640, 800, MMC 0.4*	4 hours	20 hours	24 hours
Present				
Test 1	0.0, 9.77, 19.53, 39.06, 78.13, 156.25, 312.50, 625, 1250, 2500	4 hours	20 hours	24 hours
Test 2	0.0*, 20, 40*, 80*, 160*, 320*, 480, ≥ 625, 800, CP 5*	4 hours	20 hours	24 hours

*Cultures selected for metaphase analysis.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1a	9.77, 19.53, 39.06, 78.13, 156.25, 312.50, 625, 1250, 2500	24 hours	24 hours

*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	≥ 625		≥ 625	
Test 1a	≥ 625			
Test 2		≥ 640		Positive
Present				
Test 1			≥ 1250	
Test 2		≥ 800		Positive

Remarks - Results	Qualitative observations indicate moderate dose-related inhibition of

mitotic index. There was 26% and 60% mitotic inhibition at 320 µg/mL and 480 µg/mL, respectively, in the absence of S9. In the presence of S9, 18% and 57% mitotic inhibition was observed at 160 µg/mL and 320 µg/mL, respectively.

In the chromosome aberration data, the notified chemical induced a statistically significant and dose-related increase in the frequency of cells with aberrations in the absence of metabolic activation. These increases were associated with dose related increase in mitotic inhibition. The notified chemical did not induce any statistically significant increases in the frequency of cells with abberations in the presence of metabolic activation.

The notified chemical did not induce a statistically significant increase in the numbers of polyploidy cells at any dose level in either the presence or absence of metabolic activation.

CONCLUSION

The notified chemical was clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY

Harlan (2014a)

B.9. Genotoxicity – *in vivo*

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.

Species/Strain: *Mus musculus* / albino Hsd:ICR (CD-1®)
Route of Administration: Oral – gavage
Vehicle: Arachis oil
Remarks - Method: Exception to GLP standards – No analysis was conducted to determine the homogeneity, concentration or stability of the notified chemical formulation.

The micronucleus test was conducted using the oral (gavage) route in groups of seven mice at the maximum recommended dose of 2,000 mg/kg, with 1,000 and 500 mg/kg as the lower dose levels. Animals were killed 24 or 48 hours later, the bome marrow extracted, and smear preperations made and stained. Polychromic (PCE) and normochromatic (NCE) erythrocytes were scored for the presence of micronuclei.

Additional groups of mice were given a single oral dose of arachis oil (7 mice), or dosed orally with cyclophosphamide (5 mice), to serve as vehicle and positive controls respectively. Vehicle control animals were killed 24 hours later, and positive control animals were killed after 24 hours.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	7	0.0	24
II (low dose)	7	500	24
III (mid dose)	7	1,000	24
IV (high dose)	7	2,000	24
V (high dose)	7	2,000	48
VI (positive control, CP)	5	50	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	The clinical signs observed in animals dosed with the notified chemical at 2,000 mg/kg via the oral route were as follows: hunched posture, ptosis, ataxia tip-toe gait and splayed gait. The confirmatory male animals were dosed with the notified chemical at 2,000 mg/kg and the clinical signs of hunched posture, ptosis, ataxia and splayed gait were observed. The notified chemical showed no marked difference in its toxicity to male or female mice. There were no premature deaths seen in any of the dose groups. The following clinical signs were observed at and above 1,000 mg/kg in both the 24 and 48-hour dose groups: hunched posture, ptosis, ataxia and splayed gait.
Genotoxic Effects	Statistically significant decreases in the PCE/NCE ratio were not observed in any of the notified chemical dose groups when compared to the vehicle control group. Observations of clinical signs were taken to indicate that systemic absorption had occurred and exposure to the target tissue had been achieved.
Remarks - Results	There was no evidence of any statistically significant increases in the incidence of micronucleated polychromatic erythrocytes in animals dosed with the notified chemical when compared to the vehicle control group. The positive control group showed a marked increase in the incidence of micronucleated polychromic erythrocytes, confirming the sensitivity of the system to the known mutagenic activity of cyclophosphamide under the conditions of the test.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this *in vivo* Mammalian Erythrocyte Micronucleus Test.
TEST FACILITY	Harlan (2014b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	Nil
Analytical Monitoring	CO_2 Evolution
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

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
8	7	8	57
10	51	10	74
14	45	14	63
28	44	28	62
29*	46	29*	63

* Day 29 values corrected to include any carry-over of CO_2 detected Absorber 2

Remarks - Results	All validity criteria for the test were satisfied. The toxicity control exceeded 25% biodegradation (required by guideline) showing that toxicity was not a factor affecting the low biodegradability of the test substance. The mean cumulative net CO_2 evolved (percent biodegradation) from the aqueous medium fortified with test substance at 10 mg C/L was 46% after 28 days. It did not pass the criterion for ready biodegradability of ≥ 60% degradation (CO_2) reached within the 10 day window within the 28 days of the test. Therefore, the test substance cannot be classified as readily biodegradable according to the OECD 301 B (1992) guideline.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	Harlan (2012b)

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 Test
Species	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	Not reported
Water Hardness	140 mg $CaCO_3$/L
Analytical Monitoring	ICP-MS 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. The fish ecotoxicity test was conducted in Water Accommodated Fractions (WAFs) of the test substance as it is a complex mixture and has low water

solubility. WAFs of nominal loading rate were prepared by stirring the test substance in water for 23 hours followed by a 1-hour settlement period. WAF treatment solutions were separated from mixtures by siphoning to give the 100 mg/L loading rate WAF. Microscopic inspection of the WAF showed no micro-dispersions or undissolved test item to be present.

RESULTS

Nominal Concentration (WAF;mg/L)	*Number of Fish*	*Mortality (%)*				
		3 h	*24 h*	*48 h*	*72 h*	*96 h*
Control	7	0	0	0	0	0
100	7	0	0	0	0	0

LL50 > 100 mg/L at 96 hours
NOEL 100 mg/L at 96 hours
Remarks – Results All validity criteria for the test were satisfied. The ecotoxicity test was conducted as a limit test. The actual concentrations of the test substance in WAFs were measured at 0 and 72 hours (fresh media) and at 24 and 96 hours (old media). However, median lethal loading rate (LL50) and no observed effect loading rate (NOEL) values were estimated, by visual observations, 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.

After siphoning and for the duration of the test, the 100 mg/L loading rate was observed to be clear and colourless.

CONCLUSION The chemical is not harmful to fish

TEST FACILITY Harlan (2014c)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static Test
Species *Daphnia magna*
Exposure Period 48 hours
Auxiliary Solvent Not reported
Water Hardness 250 mg $CaCO_3$/L
Analytical Monitoring ICP-MS 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
1.0	20	0	0
1.8	20	0	0
3.2	20	0	0
5.6	20	5	5
10	20	0	0
18	20	0	0
32	20	10	15
56	20	0	0
100	20	30	70

EC50	83 (73–95) mg/L at 48 hours
NOEC	-
Remarks – Results	All validity criteria for the test were satisfied. The concentrations of the test substance were measured at 0 and 48 hours. Given that a measured concentration of 80% of the nominal concentration was obtained at 48 hours, only nominal test concentrations were used in this study. The 48-hour EC_{50} was calculated by the trimmed Spearman-Karber method (1977). The NOEC value provided was not reliable. Hence, it is not included in the study summary.

CONCLUSION	The notified chemical is harmful to aquatic invertebrates
TEST FACILITY	Harlan (2012c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours
Concentration Range	Nominal: 6.25, 12.5, 25, 50, and 100 mg/L
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	ICP-MS 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)*
18	6.25	51	6.25

Remarks – Results	All validity criteria for the test were satisfied. Analysis of the treatments at 0 and 72 hours showed that 94% to 98% of the nominal concentration was obtained. Therefore, nominal concentrations were used to calculate the end points. One way analysis of variance for homogeneity of variance was done. Dennett's multiple comparison procedure (1955) for comparing several treatments with the control to determine any statistically significance differences between the treatment and control groups. The 100 mg/L test concentration was not included in the analysis as visual inspection of the data showed a significant effect on growth. EC50 values were determined using linear interpolation method.

CONCLUSION	The notified chemical is harmful to algae
TEST FACILITY	Harlan (2012d)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test
Inoculum	Aerobic activated sludge
Exposure Period	3 hours

Concentration Range	Nominal: 10, 100, and 1000 mg/L
Remarks – Method	The test was conducted following the test guidelines and good laboratory practice (GLP) principles.

RESULTS

EC50	> 1,000 mg/L
NOEC	100 mg/L
Remarks – Results	All validity criteria for the test were satisfied. No inhibition of the bacteria respiration was observed during the 3-hour test at all the test concentrations.

CONCLUSION	The product containing the notified chemical is not inhibitory to the sludge bacteria respiration
TEST FACILITY	Harlan (2013b)

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