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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

CP 5076

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.

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

TABLE OF CONTENTS

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/1540	Cintox Australia Pty Ltd	CP 5076	ND*	≤ 10 tonnes per annum	Component of engine oils

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no toxicity data on the notified chemical were provided, the notified chemical cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS).

Based on the information on the (Material) Safety Data Sheet ((M)SDS) provided by the notifier, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R36: Irritating to eyes
R38: Irritating to skin

Human health risk assessment
Provided that the recommended controls are being adhered to, 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 reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - R36: Irritating to eyes
  - R38: Irritating to skin

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

- Due to the environmental hazardous properties of the notified chemical, the notifier should consider their obligations under the Australian Dangerous Goods Code (NTC, 2014) when introducing the notified chemical in a form that meets the dangerous goods criteria.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical during reformulation:

- Enclosed, automated processes, where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation and use:
  - Avoid contact with skin and eyes

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during reformulation and use:
  - Protective clothing
  - Impervious gloves
  - Eye protection

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified chemical should be disposed of in accordance with local regulations for recycling, re-use or recovery of calorific content.

Storage

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

Emergency procedures

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

Transport and Packaging

- Transport and packaging of the notified chemical should be in accordance with Australian Dangerous Goods Code (NTC, 2014).

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

- toxicological data for the notified chemical becomes available; and
- the concentration of the notified chemical in engine oil products for consumers > 1%.

or

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

- the function or use of the chemical has changed from a component of engine oils, 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)
Cintox Australia Pty Ltd (ABN: 63 122 874 613)
Suite 1, Level 2
38-40 George Street
PARRAMATTA NSW 2150

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, impurities, import volume and identities of analogues.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: vapour pressure, adsorption/desorption, dissociation constant, flash point, flammability, autoignition temperature, explosive properties, oxidising properties and all (eco)toxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CP 5076

OTHER NAME(S)
Borated polyalkylamido polyol

MOLECULAR WEIGHT
Representative structure < 500 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC, GC-MS, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Amber liquid

Property	Value	Data Source/Justification
Melting Point (Pour Point)	6 °C	Measured
Boiling Point	280°C (decomp.) and 500 °C (consumed) at 101.3 kPa	Measured
Relative Density	1.06 at 20 °C	Measured
Vapour Pressure	3.45×10^{-5} kPa at 25 °C	Calculated using MPBVP v 1.43
Water Solubility	1.62 g/L at 25 °C	Measured. The notified chemical is expected to be water dispersible based on its amphiphilic structure.
Hydrolysis as a Function of pH	$t_{½}$ < 1 hour (pH 4, 7 and 9)	Measured
Partition Coefficient	log Pow = 3.57	Measured. Expected to partition to the

(n-octanol/water)		interface between octanol and water, based on its surfactant properties
Adsorption/Desorption	Not determined	Expected to partition to phase boundaries, based on its surfactant properties.
Dissociation Constant	Not determined	The notified chemical does not contain dissociable functionalities.
Stability in Organic Solvents	Stable at a nominal 1 g/L in methanol and a nominal 0.2 g/L solution in Hexane for at least 30 days at 25 ± 2 °C	Measured
Surface Tension	29.7 mN/m at 20 °C	Measured
Viscosity	1.02×10^4 mm^2/s at 40 °C 1.31×10^4 mm^2/s at 60 °C	Measured
Flash Point	159 °C	(M)SDS
Autoignition Temperature	358 °C	(M)SDS
Explosive Properties	Not determined	Does not contain functional groups that imply explosive properties.
Oxidising Properties	Not Determined	Does not contain functional groups that imply oxidising properties.

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemical is hydrolytically unstable; however, it is expected to be stable under normal conditions of the proposed use.

Physical hazard classification

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

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be introduced into Australia as a component of additive packages for engine oil (at ≤ 10% concentration) or as a component of finished engine oil products (at ≤ 1% concentration).

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

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

PORT OF ENTRY

Typical ports of entry will include Sydney, Melbourne, Perth and Brisbane

TRANSPORTATION AND PACKAGING

The additive packages and end-use engine oils containing the notified chemical will be transported into Australia by sea either in 20,000 L isotanks which will be unloaded to tank trucks or rail cars for distribution or in drums (such as steel 205 L) for delivery to customers.

USE

The notified chemical will be used as a component of engine oils at ≤ 1% concentration for automotive use.

OPERATION DESCRIPTION

The notified chemical will not be manufactured in Australia, but the additive packages will be reformulated after importation.

Reformulation
After importation additive packages containing the notified chemical (at ≤ 10%) will be transferred into storage tanks through hoses with air back flush systems to prevent spillage, before being transferred into the blending facilities and formulated into engine oil products by mixing with oil and other additives. Transfer from the storage tanks to the blending facilities and the blending process itself is expected to involve automated, well ventilated and enclosed systems. The resulting engine oil products containing the notified chemical (≤ 1%) will be filled into 205 L drums and smaller containers (such as 1 L and 4 L plastic bottles) which will be distributed to end-users. Samples may be taken during the blending process for quality control testing.

End use
Engine oil products containing ≤ 1% of the notified chemical will primarily be used by the public, and to a lesser extent, commercial automotive and industrial engine service outlets. Use by the public will involve the engine oils being manually decanted into automobile engines, while at industrial sites the engine oils will be pumped from the drums.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

Transport and storage workers may come into contact with the notified chemical (≤ 10%) only in the event of accidental rupture of containers.

Reformulation
Dermal and ocular exposure of workers to the notified chemical at ≤ 10% concentration may occur during reformulation when connecting and disconnecting hoses and during sample testing. The blending process is expected to be automated and within a closed system.

Dermal and ocular exposure to workers should be mitigated through the engineering controls such as the use of a special air back flush system to prevent spillage during transfer and the used of personal protective equipment (PPE) including protective clothing, impervious gloves and googles, as anticipated by the notifier in the application dossier. Inhalation exposure is not expected given the calculated low vapour pressure of the notified chemical. Inhalation exposure potential will be further limited by the notifier anticipated use of local exhaust ventilation.

End-use
At automotive service centres, professional users such as mechanics may experience dermal or ocular exposure to the engine oil products containing the notified chemical (≤ 1% concentration) when transferring engine oil to cars. The potential for dermal and ocular exposure may be mitigated through the use of PPE (e.g. gloves, protective clothing and goggles), as anticipated by the notifier in the application dossier.

6.1.2. Public Exposure
If members of the public change/top up engine oil in vehicles they may experience limited dermal and accidental ocular exposure to the notified chemical at concentrations ≤ 1%. However, given the low concentration (≤ 1%) of the notified chemical in the oils and the fact that the engine oil is changed infrequently, potential for exposure to the notified chemical is low.

6.2. Human Health Effects Assessment
No toxicity data were submitted for the notified chemical. The results from toxicological investigations conducted on the analogues of the notified chemical (identities of the analogues are in Exempt Information; the analogues are either constituents of the notified chemical or structurally similar to it) are summarised in the following table. For full details of the studies, refer to Appendix B. As the analogues are not considered to be suitable to individually read-across for the notified chemical, the following toxicity data for the analogues, combined with other toxicity data for the constituents of the notified chemical which contain the functional groups of concern, are considered as weight of evidence to estimate the toxicity of the notified chemical as a worst scenario.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity*	LD50 > 5000 mg/kg bw; low toxicity

Rat, acute oral toxicity[#]	LD50 > 5000 mg/kg bw; low toxicity
Rat, acute dermal toxicity*	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity[#]	LD50 > 5000 mg/kg bw; low toxicity
Rabbit, skin irritation[#]	irritating
Rabbit, eye irritation[#]	slightly irritating
Guinea pig, skin sensitisation – adjuvant test[#]	no evidence of sensitisation
Rat, repeat dose dermal toxicity – 14 weeks*	LOAEL (local irritation) = 25 mg/kg bw/day NOAEL (local irritation) = not established NOAEL (systemic toxicity, males) = 400 mg/kg/day (highest dose tested) LOAEL (systemic toxicity, females) = 25 mg/kg/day (based on absolute kidney weight changes) NOAEL (systemic toxicity, females) = not established
Rat, repeat dose dermal toxicity – 104 weeks*	LOAEL (local irritation) = 50 mg/kg/day NOAEL (local irritation) = Not established NOAEL (systemic toxicity, males) = 100 mg/kg/day (highest dose tested) LOAEL (systemic toxicity, females) = 50 mg/kg/day (based on increased incidence of renal tubule hyperplasia) NOAEL (systemic toxicity, females) = not established
Mouse, repeat dose dermal toxicity – 14 weeks*	LOAEL (local irritation) = 50 mg/kg/day NOAEL (local irritation) = not established LOAEL (systemic toxicity) = 400 mg/kg/day (based on increased liver and kidney weight) NOAEL (systemic toxicity) = 200 mg/kg/day
Mouse, repeat dose dermal toxicity – 104-105 weeks*	LOAEL (local irritation) = 100 mg/kg/day NOAEL (local irritation) = Not established NOAEL (systemic toxicity) = Not established (organ weights, basis for NOAEL in 14-week study, were not measured)
Rat, repeat dose dermal toxicity – 90 days[#]	NOAEL = 1 mL/kg bw/day
Mutagenicity – bacterial reverse mutation*	non mutagenic
Mutagenicity – bacterial reverse mutation[#]	non mutagenic
Genotoxicity – in vitro mammalian cell gene mutation assay*	non genotoxic
Genotoxicity – in vitro chromosome aberration study*	non genotoxic
Genotoxicity – in vitro sister chromatid change assay*	non genotoxic
Genotoxicity – in vivo micronucleus assay*	genotoxic
Rat, developmental toxicity*	LOAEL (maternal toxicity = 1000 mg/kg/day NOAEL (maternal toxicity) = 300 mg/kg/day LOAEL (developmental toxicity) = 100 mg/kg/day (mortality and post-implantation loss) NOAEL (developmental toxicity) = not established
Carcinogenicity*	non carcinogenic (male rats)/equivocal (female rats)/carcinogenic (mice)

* Data for Analogue 1
[#] Data for Analogue 2

Toxicokinetics.
No data on toxicokinetics for the notified chemical was provided. For dermal absorption, molecular weights below 500 are favourable for absorption and molecular weights above 1000 do not favour absorption (ECHA, 2012). Dermal uptake is likely to be low if the water solubility is below 1 mg/L and the rate of penetration may be limited by the rate of transfer between the stratum corneum and the epidermis if log P values are above 4 (ECHA, 2012). Based on the molecular weight (< 500 for the representative structure), water solubility (1.6 g/L at 20 °C) and partition coefficient (log Pow = 3.57 at 20 °C) of the notified chemical, absorption across biological membranes is expected.

Acute toxicity.
No acute toxicity data was provided for the notified chemical.

For Analogue 1, the acute oral toxicity in rats and the acute dermal toxicity in rabbits are low (LD50 > 5000 mg/kg bw and LD50 > 2000 mg/kg bw, respectively) (US EPA, 2010 and ACC, 2001).

Analogue 2 was found to be of low toxicity via the oral and dermal routes in rats.

Irritation and sensitisation.
No Irritation or sensitisation data was provided for the notified chemical. Analogue 2 was found to be irritating to the skin of rabbits and slightly irritating to the eyes of rabbits.

Analogue 2 did not cause skin sensitisation in guinea pigs (adjuvant test using the Magnusson and Kligman method).

Repeated dose toxicity.
No repeated dose toxicity data for the notified chemical was submitted.

In repeated dose dermal toxicity studies in rats and mice with Analogue 1, the No Observed Adverse Effect Level (NOAEL) for systemic toxicity was not established based on changes in organ weights (especially kidney and liver) at 25 mg/kg/day and above. Local irritation was observed in the studies at 25 mg/kg/day and above and the NOAEL for local irritation was not established (US EPA, 2010).

For Analogue 2 the dermal NOAEL for was not established in the study based on skin irritation seen at all dose levels. However, no test substance related significant systemic effects at any of the doses administered (up to 1 mL/kg bw/day) were noted, and hence the NOAEL for systemic effects was established as > 1 mL/kg bw/day in this study.

Based on the conflicting data on Analogue 1 and 2 the notified chemical may produce adverse systemic toxicity following repeated dermal exposure.

Mutagenicity/Genotoxicity.
No mutagenicity/genotoxicity data for the notified chemical was submitted.

Analogue 1 was negative for gene mutations in bacteria, mammalian cells *in vitro*, chromosomal aberrations *in vitro*, and sister chromatid exchange *in vitro* but was positive in a mouse micronucleus assay *in vivo* (US EPA, 2010).

Analogue 2 was not mutagenic in a bacterial reverse mutation study.

Carcinogenicity.
No carcinogenicity data for the notified chemical was submitted.

Analogue 1 was carcinogenic in mice, equivocal in female rats and negative in male rats (US EPA 2010). The positive result in mice was considered by the study authors to be associated with the concentration of free Constituent 2 of the notified chemical present as a contaminant in the test substance of Analogue 1 (NTP, 2001). The purity of the notified chemical provided by the notifier is > 99% and Constituent 2 is not a readily hydrolysed product of the notified chemical according to a HPLC analysis provided by the notifier and as expected from the chemical structure of the notified chemical. Therefore the carcinogenicity seen in the mice with Analogue 1 may not be a concern of the notified chemical.

Reproductive and Developmental Toxicity.
No reproductive and developmental toxicity data were submitted for the notified chemical.

No specific reproductive toxicity studies are available for Analogue 1; however, in the 14-week repeated-dose toxicity studies in rats and mice, no effects on reproductive organs were observed (US EPA, 2010).

The NOAEL for maternal toxicity was established as 300 mg/kg/day in an oral rat prenatal developmental toxicity study with Analogue 1 based on treatment-related clinical effects (salivation and propulsion of the head) were noted in the dams at 1000 mg/kg/day (US EPA, 2010). The NOAEL for developmental toxicity was not

established and post-implantation loss and embryonic deaths were seen at 100 mg/kg/day and above, with statistically significant retardation in ossification observed at 300 mg/kg/day and above (US EPA, 2010).

In another developmental toxicity study conducted on Analogue 1, both maternal and developmental No Observed Adverse Effect Levels (NOAELs) were established by the study authors as 1000 mg/kg bw/day in rats via the oral route (the highest dose tested) based on the absence of test substance related toxicologically significant effects at any of the doses administered (ACC, 2001).

Constituent 4 (identity in Exempt Information) of the notified chemical (not a constituent of Analogue 1) is classified in HSIS as R60 – may impair fertility and R61- may cause harm to unborn child at a cut-off concentration ≥ 5.5%. The notified chemical readily hydrolyses on contact with water or atmospheric moisture, and constituent 4 is a readily hydrolysed product of the notified chemical according to the HPLC analysis provided by the notifier. Therefore the reproductive and developmental toxicity of Constituent 4 is considered to be a concern of the notified chemical.

Based on the conflicting data on Analogue 1 and the hazardous properties of Constituent 4 the notified chemical may produce adverse reproductive and developmental effects.

Health hazard classification
As no toxicity data were provided for the notified chemical, the notified chemical cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on available data for the analogues and constituents of the notified chemical, the notified chemical is expected to have low acute oral and dermal toxicity. It is not expected to be a skin sensitiser. It is an irritant to the skin and eyes as stated in the MSDS provided by the notifier and supported by the data on analogue 2. Genotoxicity and systemic toxicity (including reproductive and developmental toxicity) cannot be ruled out.

There is potential for dermal and ocular exposure to the notified chemical at concentrations up to 10% during importation, loading/unloading, transfer, blending and QA testing, and concentrations up to 1% during packaging, transportation and use of end-use products. However, the notifier anticipated use of personal protective equipment (PPE) (gloves, safety glasses and protecting clothing) and engineering controls (largely automated and enclosed systems and local exhaust ventilation) should minimise exposure. Inhalation exposure may occur if mists are generated during formulation processes and the notifier anticipated use of respiratory protection should mitigate this.

Overall, considering the proposed use of engineering controls and PPE, and the low concentration of the notified chemical in products during packaging and end-use, the risk to workers from reformulation and use of the notified chemical is not considered unreasonable.

6.3.2. Public Health
Given the public will only be exposed to the notified chemical at low concentrations (≤ 1%) and on an infrequent basis, the risk to public health from use of the notified chemical is not considered unacceptable.

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 for repackaging and reformulation into engine lubricating oils. Significant release of the notified chemical to the environment is not expected during transport and storage except in the unlikely event of accidental spills or leaks.

Any notified chemical spilled during reformulation is expected to be contained with concrete bunds and either reclaimed or sent to on-site waste treatment facilities. At the on-site waste treatment facilities, residues of the notified chemical will be separated from the aqueous waste stream by the American Petroleum Industry (API) process. As a result of this treatment, greater than 90% removal of the notified chemical is estimated by the notifier. The aqueous waste undergoes further treatment involving pond aeration and biological treatment before being released to the sewage system. The remaining non-aqueous waste is expected to be disposed of according to local regulations. Therefore, the accidental release from reformulation of the notified chemical and finished oils is unlikely to be significant.

RELEASE OF CHEMICAL FROM USE
The finished products containing the notified chemical will be used as a component of engine lubricants. Release during its use may come from spills when pouring lubricants into engines or leaks from the engines, which is expected to be negligible.

RELEASE OF CHEMICAL FROM DISPOSAL
After reformulation, empty import drums containing residues of the notified chemical (0.1% of the total import volume) are expected to be steam cleaned, with the residual waste sent to on-site wastewater treatment facilities. Assuming 0.1% of the notified chemical remains in the empty drums after use, 10 kg/yr (10 tonnes/yr × 0.1%) of the notified substance will be sent to the on-site waste treatment. It is estimated by the notifier that greater than 90% of the notified chemical may be removed during waste treatment processes. Therefore, the amount of the notified chemical released to sewer from the cleaning of empty drums is estimated to be 1 kg/yr (= 200 kg/year × 10%). The wastewater will be further treated at the sewage treatment plants. Therefore, the release of the notified chemical to surface waters is expected to be limited from the cleaning of empty drums.

The major release of the notified chemical to the environment will come from inappropriate disposal of waste or used oils. Oil products containing the notified chemical will be poured into engines by automotive service centres or by do-it-yourself (DIY) consumers. A survey by the Australian Institute of Petroleum (AIP, 1995) indicates that of the annual sales of engine oils in Australia, 60% of oils are potentially recoverable (i.e. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases is disposed of responsibly (e.g. oil recycling or incineration). Assuming this is the case, negligible release of the notified chemical should result from these professional activities. The remaining 14% of oil is removed by DIY consumers. In these cases, some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. It was estimated that DIY activities account for 7 - 10% of the unaccounted used oil (Meinhardt, 2002).

According to a survey tracing the fate of used lubricating oil in Australia (Snow 1997), only approximately 20% of used oil removed by DIY consumers is collected for recycling, approximately 25% is buried or disposed of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways. In a worst case scenario involving the 14% of used oil removed by DIY consumers, up to 0.7% (= 14% × 5%) of the total import volume of the notified chemical may enter the aquatic environment via disposal to stormwater drains. Therefore, the amount of the notified chemical released to the aquatic environment from disposal of used oil due to DIY consumers is expected to be 70 kg/yr (= 10 tonnes/year × 0.7%). In addition to this, considering the unknown fate of some of the oil used by DIY consumers, a small proportion may also be disposed of to the sewer. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified chemical in neat concentrations is unlikely except as a result of transport accidents.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified chemical. However, an environmental fate study for Analogue 2, was submitted. The analogue was considered to be readily biodegradable based on the reported study. For the details of the environmental fate study please refer to Appendices C. Therefore, the notified chemical has potential to be readily biodegradable. The notified chemical is hydrolysable in unstable environmental conditions.

The majority of the notified chemical will be thermally decomposed during usage in engine oils, or thermally decomposed to recover the calorific value, or disposed of to landfill. In landfill, the notified chemical is not expected to leach from soil due to its surfactant properties. The notified chemical is expected to degrade in landfill or be thermally decomposed to form water and oxides of carbon, boron and nitrogen. Based on its surface active properties, the notified chemical is likely to partition to phase boundaries, and therefore expected to partition to sludge during sewage treatment processes. The notified chemical released to surface waters is

expected to partition to sediment. Additionally, the notified chemical is not expected to bioaccumulate based on its surfactant property. Any notified chemical remaining in treated sewage effluents is likely to be released to surface waters or applied to land when used for irrigation. Notified chemical in sewage sludge is anticipated to be disposed of to landfill or applied to land when sludge is used for soil remediation.

7.1.3. Predicted Environmental Concentration (PEC)

For the worst case scenario, the percentage of the imported quantity of notified chemical inappropriately disposed to stormwater drains is estimated to be 0.7%. That is, 14% (fraction collected by DIY users) × 5% (fraction disposed to stormwater). The release of the notified chemical may be up to 70 kg/year (= 10 tonnes/year × 0.7%). In this worst case scenario, it is assumed that the release goes into stormwater drains in a single metropolitan area with a geographical footprint of 500 km^2 and an average annual rainfall of 500 mm, all of which drains to stormwater. With a maximum annual release into this localised stormwater system of 70 kg and the annual volume of water drained from this region estimated to be 250 × 10^6 m^3, the calculated PEC will be up to 0.28 µg/L. This result reflects a worst-case scenario upper limit, as in reality releases of the notified chemical will be distributed over multiple regional/farming areas and it will be further diluted if it reaches the ocean.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted for the notified chemical. Ecotoxicity data for fatty alkanolamides, fatty acid, diethanolamide (Cocoamide DEA) are available in Madsen et al. (2001, p 68). The ecotoxicity results for Cocoamide DEA are summarised in the table below. Analogue 2 does not contain a diethanolamide functional group, which is expected to be toxic to aquatic species. Therefore, the endpoints presented below are not expected to reflect the ecotoxicity of the notified chemical and were not read across in this assessment. However, the analogue data illustrate that the borate ester functional group does not exhibit ecotoxicological effects to the aquatic organisms. Details of the studies for the Analogue 2 can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Notified chemical		
Inhibition of Bacterial Respiration	EL50 = 310 mg/L	Not inhibitory to microbial respiration
Cocoamide DEA		
Fish	3.6 mg/L	Expected to be toxic to fish
Daphnia	2.4 mg/L	Expected to be toxic to aquatic invertebrates
Algae	2.2 mg/L	Expected to be toxic to algae
Analogue 2		
Fish	LL50 (96 h) > 1,000mg/L *	Not harmful to fish
Daphnia	LL50 (48 h) > 1,000 mg/L*	Not harmful to aquatic invertebrates

*Water Accommodated Fraction (WAF)

The notified chemical is a mixture of homologous compounds. As there are no specific ecotoxicity endpoints for this mixture of compounds, it is not appropriate, in this case, to classify the notified chemical for acute or long-term aquatic hazards under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified chemical has been calculated and presented in the table below. An assessment factor of 100 has been used to derive the PNEC as ecotoxicity data for aquatic species at three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga)	2.2	mg/L
Assessment Factor	100	
PNEC:	22	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:	0.28	22	0.013
Q - Ocean:	0.028	22	0.0013

The Risk Quotients (Q = PEC/PNEC) have been calculated to be < < 1 for both river and ocean compartments. The notified chemical is not expected to persist in the environment as it is hydrolysable, and is not expected to bioaccumulate. Therefore, on the basis of the PEC/PNEC ratio, maximum annual import volume and assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point (Pour Point) 6 °C

Method OECD TG 102 Melting Point/Melting Range.
Remarks Pour point determined for oily test substance. Determined by an automatic pour point apparatus.
Test Facility Chevron (2014a)

Boiling Point Decomposition begins at 280 °C; Consumed by at 500 °C

Method OECD TG 103 Boiling Point.
Remarks Thermogravimetric analysis.
Test Facility Chevron (2014a)

Relative Density 1.06 at 20 ± 0.5 °C

Method OECD TG 109 Density of Liquids and Solids.
EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks Pycnometer method
Test Facility Harlan (2013)

Water Solubility 1.62 g/L at 25 °C

Method OECD TG 105 Water Solubility.
EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Flask Method
Test Facility Chevron (2014b)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	$t_{½}$
4	At room temperature	< 1 hour
7	At room temperature	< 1 hour
9	At room temperature	< 1 hour

Remarks The standard and sample solutions were analysed by HPLC as well as ICP-MS system. The test item was hydrolysed almost instantly; it was not possible to use the data to determine a definitive rate of hydrolysis. The half life has therefore been reported as a worst case of less than 1 hour, the duration of the investigation
Test Facility Harlan (2014a)

Partition Coefficient (n-octanol/water) log Pow = 3.57

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks HPLC Method
Test Facility Chevron (2014c)

Viscosity 1.02×10^4 mm^2/s at 40 ± 0.5 °C; 1.31×10^4 mm^2/s at 60 ± 0.5 °C

Method OECD TG 114 Viscosity of Liquids.
Remarks The test system consisted of a certified glass capillary viscometer.
Test Facility Harlan (2014a)

Surface Tension 29.7 mN/m at 20.8 ± 0.5 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions. EC Council Regulation No 440/2008 A.5 Surface Tension.
Remarks	Concentration: 90%
Test Facility	Harlan (2014a)

Stability in Organic Solvents Stable at a nominal 1 g/L in methanol and a nominal 0.2 g/L solution in Hexane for at least 30 days at 25 ± 2 °C

Method	In-house
Remarks	Concentration determined by HPLC. Conclusion drawn from the absence of any significant change (< 10%).
Test Facility	Harlan (2014a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE Analogue 2

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain Rat/ Sprague Dawley
Vehicle None
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	0	0/10
2	5 per sex	5,000	0/10

LD50 > 5,000 mg/kg bw
Signs of Toxicity There were no mortalities and no signs of treatment-related toxicity were observed.
Effects in Organs No treatment-related gross pathological changes were observed at necropsy.
Remarks - Results No significant differences were noted between body weights of treated and control groups.

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

TEST FACILITY Chevron (1982a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE Analogue 2

METHOD OECD TG 402 Acute Dermal Toxicity.
Species/Strain Rabbit/New Zealand White
Vehicle None
Type of dressing Occlusive
Remarks - Method The test material was applied to abraded skin.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	5,000	0/10

LD50 > 5000 mg/kg bw
Signs of Toxicity There were no mortalities and no signs of treatment-related toxicity were observed.
Effects in Organs No treatment-related gross pathological changes were observed at necropsy. Histopathological examination of skin sections of treated rabbits showed hyperkeratosis, a mind proliferative response of the epidermis suggesting a very mild cutaneous injury. Diffuse chronic cholangiohepatisis noted in a liver section of a treated female animal and was considered by the study authors to probably not be treatment-related.
Remarks - Results No significant differences were noted between body weights of treated and control groups.

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

TEST FACILITY Chevron (1982a)

B.3. Irritation – skin

TEST SUBSTANCE Analogue 2

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 6
Vehicle None
Observation Period 7 days
Type of Dressing Occlusive
Remarks - Method Abraded skin and intact skin sites on each animal were tested using a 24 hour exposure period.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Intact sites				
Erythema/Eschar	2.3	3	> 7 days	2
Oedema	1.9	3	< 7 days	0
Abraded sites				
Erythema/Eschar	2.3	3	> 7 days	2
Oedema	1.8	3	< 7 days	0

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

Remarks - Results Well-defined to moderate erythema and very slight to moderate edema were noted through 72 hours after treatment. At 7 days after treatment, Well-defined erythema was noted in 1 animal and dry and cracked skin was noted in 5/6 animals.

CONCLUSION The test substance is irritating to the skin.

TEST FACILITY Chevron (1982a)

B.4. Irritation – eye

TEST SUBSTANCE Analogue 2

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 9
Observation Period 7 days
Remarks - Method 0.1 mL of test substance was instilled into a single eye of the test animals. Three animals were further treated by rinsing the eye for 1 minute at a rate of 250 mL/min with distilled water 30 seconds after treatment.

RESULTS

Treated-unrinsed

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0	1	< 24 hours	0
Conjunctiva: chemosis	0	0	-	0
Conjunctiva: discharge	0	1	< 24 hours	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Treated-rinsed

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0	1	< 24 hours	0
Conjunctiva: chemosis	0	0	-	0
Conjunctiva: discharge	0	1	< 24 hours	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Remarks - Results: Both the treated-unrinsed and the treated-rinsed eyes showed slight conjunctival irritation 1 hour after exposure. All eyes were clear by 24 hours after treatment.

CONCLUSION: The test substance is slightly irritating to the eye.

TEST FACILITY: Chevron (1982a)

B.5. Skin sensitisation

TEST SUBSTANCE: Analogue 2

METHOD: OECD TG 406 Skin Sensitisation - Magnusson and Kligman

Species/Strain: Guinea pig/ albino Hartley

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 1% in peanut oil
topical: 5% in peanut oil

MAIN STUDY

Number of Animals: Test Group: 20 Control Group: 19 (20 at onset of study, mortality accounted for decrease)

INDUCTION PHASE: Induction Concentration:
intradermal: 1% in peanut oil
topical: 5% in peanut oil mixed with 0.5 g petrolatum

Signs of Irritation

CHALLENGE PHASE: topical: 0.2% in peanut oil mixed with 0.5 g petrolatum

Remarks - Method: The concentrations of the test substance used in the main study were determined in a preliminary study. The negative control for challenge was 0.2 g peanut oil. The positive control was ethylenediamine.
The test animals received two induction treatments, an intradermal injection on day 0 and a topical application on day 7.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: challenge*	
		24 h	*48 h*
Test Group	1%	0/20	0/20
Negative Control	1%	0/15*	0/15*
Positive Control	10%	16/18	17/17#

* Four animals excluded from counting as irritation was observed on both the treated and control flanks.
# one animal excluded from counting as irritation was observed on both the treated and control flanks.

REMARKS - RESULTS: One animal in the negative control and two animals in the positive control died within 48 hours of the topical induction.
There were no remarkable body weight changes in surviving animals during the study.

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

TEST FACILITY	Chevron (1982b)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Analogue 2
METHOD	Similar to OECD TG 410 Repeated Dose Dermal Toxicity: 21/28-day Study
Species/Strain	Rats/Sprague-Dawley
Route of Administration	Dermal – occluded
Exposure Information	Total exposure days: 28 days Dose regimen: 6 hours per day for an average 5 days per week Post-exposure observation period: 0 (all animals were sacrificed within 24 l after the last treatment)
Vehicle	Mineral oil
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mL/kg bw/day*	*Mortality*
control	15 per sex	0	0/15
low dose	15 per sex	0.2	0/15
mid dose	15 per sex	0.5	0/15
high dose	15 per sex	1	0/15

Clinical Observations

No signs of toxicity were noted during the study. Dose-related very slight to well-defined erythema in the skin of male and female animals was noted at the end of the week 1. Very slight edema was noted in the skin of several male animals in the high-dose group and several female animals in the high- and mid-dose groups at the end of week 1. Skin irritation had subsided by the second week and only appeared sporadically in a limited number of animals through to the end of the study.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No significant differences in the haematological parameters between control and treated animals were considered by the study authors to be treatment-related.

Effects in Organs

No significant differences were noted in mean organ weights or mean organ/body weight ratios between the control and treated males. The mean left ovary weight and mean left ovary/body weight ratio in females of the high- and mid-dose groups were significantly lower than those of the control, but no such differences for right ovaries. Mean brain weight in females of the high-dose group was significantly greater than the control, but there was no difference in the mean brain/body weight ratio between females of these two groups. These statistically significant changes were not considered by the study authors to be biologically significant.

No treatment-related gross pathological changes were noted at necropsy. Microscopic examination did not reveal any treatment-related histopathological changes.

Remarks – Results

No significant differences were noted in mean body weights or mean weekly weight gain between control and treated animals.

There were no adverse systemic effects in any of the test animals that were considered by the study authors to be treatment-related.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) for systemic effects was established as > 1 mL/kg bw/day in this study, based on an absence of treatment related adverse effects at all dose levels.

The NOAEL for local effects could not be established based on skin irritation seen at all dose levels.

TEST FACILITY Chevron (1982c)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Analogue 2

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA1538, TA98, TA100
Metabolic Activation System	S9 fraction from rats treated with Aroclor 1254
Concentration Range in Main Test	a) With metabolic activation: 10 – 10000 µg/plate b) Without metabolic activation: 10 – 10000 µg/plate
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	No significant protocol derivations. In the preliminary test on strain TA100 without metabolic activation at dose levels of 5 - 10000 µg/plate, some toxicity and compound droplets were observed at 500 and 10000 µg/plate. Therefore, dose levels of 1 - 10000 µg/plate were selected for the main test.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	> 10000	≥ 1000	negative
Present			
Test 1	> 10000*	≥ 1000	negative

* Unusual appearing lawn, patchy on all plates at all dose levels for TA1538.

Remarks - Results

Cytotoxicity
In the main study, cytotoxicity was not noted in all test strains without metabolic activation at up to 10000 µg/plate and not noted in test strains TA1535, TA1537, TA98 and TA100 at up to 10000 µg/plate with metabolic activation. In the test with metabolic activation for TA1538, unusual appearing lawn was present on all plates at all dose levels including the negative control.

Mutagenicity
No significant increases in the frequency of revertant colonies were recorded for the test substance in any of the 5 test strains without and with metabolic activation.

The concurrent positive controls gave satisfactory responses confirming the validity of the test system.

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

TEST FACILITY Chevron (1981)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue 2
METHOD	OECD TG 301 F: Ready Biodegradability: Manometric Respirometry Test
Inoculum	Activated sewage sludge
Exposure Period	28 days.
Auxiliary Solvent	Not reported
Analytical Monitoring	Shimadzu TOC 5050A TOC (Total Organic Carbon) Analyser
Remarks - Method	The test was conducted according to the guidelines above using good laboratory practice (GLP). No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*Aniline (reference substance)*	
Day	*% Degradation*	*Day*	*% Degradation*
7	39	7	51
14	60.5	14	71
28	87	28	82

Remarks - Results	All validity criteria for the test were satisfied. The reference compound, aniline, achieved > 70% degradation after 14 days, and therefore the test is considered valid for this criterion. The toxicity control achieved >60% degradation after Day 14 and, as this surpasses the pass level of 25%, the test material is considered non-inhibitory to the inoculum used in the study. The test substance achieved 87% degradation after 28 days. The percent degradation of the test substance reached 58% at the end of the 10-day window. According to the nature of the test substance, 10-day window is not applicable as stated in the OECD Guidelines for Testing Chemicals, Section 3. However, a criterion, which is that the test substance degrades biotically in the environment by > 60% in 28 days, is required to be demonstrated to meet the rapid biodegradation according to the GHS (GHS; United Nations, 2009). Therefore, the test substance can be classified as readily biodegradable according to the OECD (301 F) guideline.
CONCLUSION	Analogue 2 is readily biodegradable.
TEST FACILITY	SafePharm (2002a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 2
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	130 mg $CaCO_3$/L

Analytical Monitoring	TOC (Total Organic Carbon) 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 (WAFs) of the analogue chemical 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 by using a magnetic stirrer for 48 hours and the mixture was allowed to stand for 4 hours. WAF treatment solutions were separated from mixtures by mid-depth siphoning with the addition of a glass wool plug.

RESULTS

Nominal Concentration (WAF;mg/L)	*Number of Fish*	*Mortality (%)*				
		3 h	*24 h*	*48 h*	*72 h*	*96 h*
Control	20	0	0	0	0	0
1000	30	0	0	0	0	0

LL50	> 1000 mg/L at 96 hours (filtered WAF)
NOEL	1000 mg/L at 96 hours (filtered WAF)
Remarks – Results	All validity criteria for the test were satisfied. The toxicity test was conducted as a limit test. TOC analyses of the treatments were conducted at 0 and 24 hours. The results indicated that a soluble component of the test substance was present. However, median lethal loading rate (LL50) and no observed effect loading rate (NOEL) values were determined based on the nominal loading rates as the toxicity cannot be attributed to a single component or mixture of components but to the test substance as a whole. The 96-hour LL50 and NOEL were determined based on visual observations.

CONCLUSION Analogue 2 is not harmful to fish.

TEST FACILITY SafePharm (2002b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Analogue 2

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

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Not reported
Water Hardness	264 mg $CaCO_3$/L
Analytical Monitoring	TOC (Total Organic Carbon) 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 daphnia ecotoxicity test was conducted in Water Accommodated Fractions (WAFs) of the analogue chemical 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 by using a magnetic stirrer for 48 hours and the mixture was allowed to stand for 4 hours. WAF treatment solutions were separated from mixtures by mid-depth siphoning with the addition of a glass wool plug.

RESULTS

Nominal Concentration (WAF;mg/L)	*Number of D. magna*	*Cumulative % Immobilised*	
		24 h	*48 h*
Control	40	0	0
1000	40	0	0

EL50	> 1000 mg/L at 48 hours (filtered WAF)
NOEL	1000 mg/L at 48 hours (filtered WAF)
Remarks – Results	All validity criteria for the test were satisfied. The toxicity test was conducted as a limit test. TOC analyses of the treatments were conducted at 0 and 48 hours. The results indicated that a soluble component of the test substance was present. However, median lethal loading rate (LL50) and no observed effect loading rate (NOEL) values were determined based on the nominal loading rates as the toxicity cannot be attributed to a single component or mixture of components but to the test substance as a whole. The 48-hour LL50 and NOEL were determined based on visual observations.
CONCLUSION	Analogue 2 is not harmful to aquatic invertebrates.
TEST FACILITY	SafePharm (2002c)

C.2.3. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 10, 32, 100, 320 and 1000 mg/L
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	
EL50	310 mg/L
NOEL	100 mg/L
Remarks – Results	All validity criteria for the test were satisfied
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration up to 310 mg/L
TEST FACILITY	Harlan (2014b)

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