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December 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

9-Decenamide, *N, N*-dimethyl-

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. This notification has been carried out under the signed cooperative arrangement(s) with Canada. 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/1593	Intertek Testing Services (Australia) Pty Ltd	9-Decenamide, *N, N*-dimethyl-	Yes	< 500 tonnes per annum	Component of cleaning products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Acute Toxicity, Oral (Category 4)	H302 – Harmful if swallowed
Acute Toxicity, Dermal (Category 4)	H312 – Harmful in contact with skin
Skin Corrosion/Irritation (Category 2)	H315 – Causes skin irritation
Serious Eye Damage/Eye Irritation (Category 2)	H319 – Causes eye irritation

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrases:

R22: Harmful if swallowed
R21: Harmful in contact with skin
R38: Irritating to skin
R36: Irritating to eyes

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 2	H401 – Toxic to aquatic life

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 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:
  - Acute Toxicity, Oral (Category 4): H302 – Harmful if swallowed
  - Acute Toxicity, Dermal (Category 4): H312 – Harmful in contact with skin
  - Skin Corrosion/Irritation (Category 2): H315 – Causes skin irritation
  - Serious Eye Damage/Eye Irritation (Category 2): H319 – Causes eye irritation

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.

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:
  - Exhaust ventilation
  - Enclosed and automated system

- 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:
  - Use in a well ventilated area

- 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:
  - Coveralls
  - Eye protection
  - Impervious gloves
  - Respiratory 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 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.

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.

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 notified chemical exceeds or is intended to exceed 10% in products used by the public.

or

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

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

No additional secondary notification conditions are stipulated.

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

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS and the Department of the Environment and Energy.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Intertek Testing Services (Australia) Pty Ltd (ABN: 56 001 722 854)
218 Lorimer Street
PORT MELBOURNE VIC 3207

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year) – Approved Foreign Scheme

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: analytical data, degree of purity, residual monomers, impurities/additives, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for use of analogue data to assess human health toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (DSL, 2015)
U.S.A (TSCA 2016)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
STEPOSOL®MET - 10U

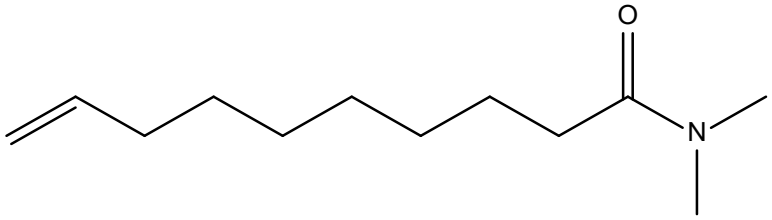
CAS NUMBER
1356964-77-6

CHEMICAL NAME
9-Decenamide, *N, N*-dimethyl-

OTHER NAME(S)
N, N-Dimethyl-9-decenamide
Steposol MET – 10U
Steposol MET – 10

MOLECULAR FORMULA
$C_{12}H_{23}NO$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
197.32 Da

ANALYTICAL DATA
Reference FTIR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Liquid

Property	Value	Data Source/Justification
Freezing Point	-11.2 °C	Measured
Boiling Point	293 °C at 102.1 kPa (decomposes)	Measured
Density	893 kg/m^3 at 20 °C	Measured
Vapour Pressure	2.4 × 10^{-4} kPa at 25 °C	Measured
Water Solubility	1.25 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	$t_{½}$ > 458 year at pH 4 $t_{½}$ > 29,163 years at pH 7 $t_{½}$ > 311 years at pH 9	Calculated for amide moieties of the notified chemical
Partition Coefficient (n-octanol/water)	log Pow = 3.17 at 30 °C	Measured; expected to partition to phase boundaries based on surface activity
Surface Tension	42.2 mN/m at 20 °C (1 g/L concentration)	Measured
Adsorption/Desorption	log K_{oc} = 2.30-2.67	Calculated based on the partition coefficient; expected to partition to soil and sediment based on surface activity
Dissociation Constant	pKa = -0.3	Calculated using ACD/I-Lab v2.0
Flash Point	146 °C at 101.3 kPa	Measured
Flammability	Not determined	Not expected to be flammable based on flash point.
Autoignition Temperature	240 °C	Measured
Explosive Properties	Predicted negative	Contains no functional groups that would imply explosive properties
Oxidising Properties	Predicted negative	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.

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 may be imported as a component of end-use products (at a concentration between 0.1 – 100%) or in pure form (100% concentration) for reformulation into end use products.

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

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

PORT OF ENTRY
Western Australia.

IDENTITY OF MANUFACTURER/RECIPIENTS
IXOM Operations Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Australia in pure form (100% concentration) or as a component of end-use products (at a concentration between 0.1 – 100%) in 55 gallon steel drums or industrial and consumer size containers. The notified chemical will be stored at Notifier's warehouse and transported by road to customers for reformulation.

USE
Intended for use in institutional and industrial cleaning products such as hard surface cleaners, industrial laundry pre-soaks, cleaning oilfield equipment; all-purpose cleaning products including bathroom cleaners, kitchen cleaners, window cleaners, speciality car care products, dilutable concentrated cleaners, dish-wash pre-soak, industrial metal cleaners and metal working fluids. Concentration of the notified chemical in products ranges from 0.1 – 100%. However, the concentration in the all-purpose cleaning products such as bathroom, kitchen and window cleaners is not expected to exceed 10%.

OPERATION DESCRIPTION
The notified chemical will not be manufactured within Australia. The imported products containing the notified chemical (at up to 100% concentration) may be repackaged or reformulated with additional components to form the finished products. Reformulation facilities are expected to be mostly automated and use closed systems. Cleaning products may be used by consumers and workers in home and industrial settings.

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)*
Reformulation and QC workers	0.15	55.5

EXPOSURE DETAILS
It is anticipated that transport and warehouse/store personnel would only be exposed to the notified chemical (at up to 100% concentration) in the event of an accident.

Reformulation workers
Dermal and ocular exposure to the notified chemical (at up to 100% concentration) may occur during connection and disconnection of transfer lines and equipment cleaning/maintenance. Exposure to the notified chemical at other times is expected to be minimised through the use of engineering controls such as enclosed and automated systems in well-ventilated areas. Exposure to the notified chemical is expected to be minimised by the use of personal protective equipment (PPE) including coveralls, face masks, gloves and safety glasses as indicated by the notifier.

End-use workers
Exposure to the notified chemical in end-use products (at up to 100% concentration) may occur in those professions providing cleaning services for industrial, commercial and/or domestic environments. The principal route of exposure will be dermal, while oral, ocular and inhalation exposure is also possible. Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified chemical (at concentrations up to 10%) through the use of household cleaning products. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible particularly if products are applied by spray.

Data on typical use patterns of product categories in which the notified chemical may be used are shown in the following table (SCSS, 2012; Cadby *et al*., 2012). For the purposes of the exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. An adult bodyweight of 64 kg was used for calculation purposes. Based on absence of dermal absorption data on the notified chemical, a dermal absorption of 100% was assumed for the notified chemical.

- Household products (Indirect dermal exposure – from wearing clothes)

Product type	**Amount** (g/use)	**C** (%)	**Product Retained (PR)** (%)	**Percent Transfer (PT)** (%)	**Daily systemic exposure** (mg/kg bw/day)
Laundry liquid	230	10	0.95	10	0.3414
Total					**0.3414**

Daily Systemic Exposure = (Amount × C × PR × PT)/body weight

- Household products (Direct dermal exposure – from wearing clothes)

Product type	**Frequency** (use/day)	**C** (%)	**Contact area** (cm^2)	**Product use C** (g/cm^3)	**Film thickness** (cm)	**Time scale factor**	**Daily systemic exposure** (mg/kg bw/day)
Laundry liquid	1.43	10	1980	0.01	0.01	0.007	0.0031
Dishwashing liquid	3	10	1980	0.009	0.01	0.03	0.0251
All-purpose cleaner	1	10	1980	1	0.01	0.007	0.2166
Total							**0.2447**

Daily Systemic Exposure = (Frequency × C × Contact area × Product Use Concentration × Film Thickness on skin × Time Scale factor × dermal absorption)/body weight

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above tables that contain the notified chemical. This would result in a combined internal dose of 0.5861 mg/kg bw/day. It is acknowledged that inhalation exposure to the notified chemical from use of household cleaning products may occur. However it is considered that the combination of conservative assessment parameters in the use of the dermally applied products, (which assumes a conservative 100% absorption rate), is sufficiently protective to cover additional inhalation exposure to the notified chemical.

6.2. Human Health Effects Assessment

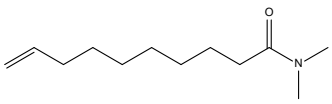
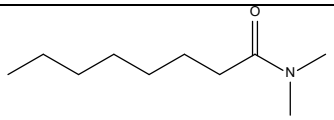
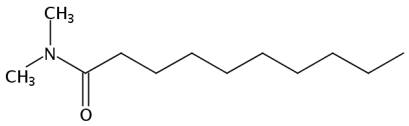
The results from toxicological investigations conducted on the notified chemical and an analogue chemical are summarised in the following table. Studies marked with an asterisk were previously assessed by Canada. For full details of the study that was not assessment by Canada, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 = 550 mg/kg bw; harmful*
Rat, acute dermal toxicity	LD50 = 2000 mg/kg bw (males)/400 - 2000 mg/kg bw (females); harmful*#
Rat, acute inhalation toxicity	LC50 > 3.6 mg/L/4 hour; harmful*#
Skin irritation (in vitro)	irritating*
Eye irritation (in vitro)	irritating
Mouse, skin sensitisation – LLNA	no evidence of sensitisation*
Rat, repeat dose oral toxicity – 90 days	NOAEL = 136.8 mg/kg bw/day*#
Mutagenicity – bacterial reverse mutation	non mutagenic*
Genotoxicity – *in vitro* chromosome aberration test	non genotoxic*#
Genotoxicity – *in vivo* mouse micronucleus test	non clastogenic*
Developmental/Reproductive toxicity	NOAEL (Maternal) = 150 mg/kg bw/day*# Developmental = equivocal*#
Developmental/Reproductive toxicity	NOAEL (Maternal) = 300 mg/kg bw/day*# Developmental = equivocal*#

* Assessed by Canada
# Data of the analogue chemical

The analogue chemical (Analogue 1) contains approximately 54% octanamide, *N,N*-dimethyl- (CAS No. 1118-92-9) and approximately 39% decanamide, *N,N*-dimethyl- (CAS No. 14433-76-2) and has similar structure and physical-chemical properties to the notified chemical. Differences between the notified chemical and Analogue 1 include lack of terminal double bond and variation in chain length (for octanamide, *N,N*-dimethyl-). The combination of the close structural similarity and similar physical-chemical properties supports the expectation that the general toxicological properties of the notified chemical and Analogue 1 will not be markedly different.

Comparison of structure and physicochemical properties of the analogue chemical with the notified chemical

	Notified Chemical	**Analogue 1**
Chemical Name	9-Decenamide, *N,N*-dimethyl-	Octanamide, *N,N*-dimethyl- and Decanamide, *N,N*-dimethyl-
Structural Formula		 octanamide, *N,N*-dimethyl-  decanamide, *N,N*-dimethyl-
Molecular Weight	197.32 Da	171.28 Da (octanamide, *N,N*-dimethyl-) 199.33 Da (decanamide, *N,N*-dimethyl-)
Density	893 kg/m^3 at 20 ^{0}C	880 kg/m^3 at 25 ^{0}C
Boiling Point	293 ^{0}C	240 - 263 ^{0}C
Vapour Pressure	2.4 × 10^{-4} kPa at 25 °C	1 × 10^{-2} kPa at 25 °C

Toxicokinetics

No information on the toxicokinetics of the notified chemical was provided. For dermal absorption, molecular weights below 100 Da are favourable for absorption and molecular weights above 500 Da do not favour absorption (ECHA, 2014). Water solubility above 1 g/L and log Pow values between 1 and 4 suggest that a substance is likely to be sufficiently lipophilic and water soluble enough to cross the stratum corneum, and epidermis and dermal absorption is likely to be high (ECHA, 2014). Therefore, there is potential for the notified

chemical to cross biological membranes based on the low molecular weight (197.32 Da), water solubility (1.25 g/L at 20 °C) and partition coefficient (Log Pow = 3.17 at 30 °C).

Acute toxicity.
An acute oral toxicity study was conducted on the notified chemical with Sprague Dawley rats according to the up-and-down procedure. The test substance was administered once by gavage to female rats (3 females/dose; 4 females at 550 mg/kg bw) at dose levels of 2000, 550 or 175 mg/kg bw. All animals died at 2000 mg/kg bw. At the highest dose, staining around the anal area was observed and at necropsy the stomach and gastrointestinal tract was distended with gas and fluid. No other gross changes were observed. At 550 mg/kg bw 2/4 rats died. All rats survived at the lowest dose tested. At the mid and low dose, there were no external or internal gross changes observed. The acute oral LD50 was considered to be 550 mg/kg bw and it was concluded that the test substance exhibited moderate oral toxicity to rats.

An acute dermal toxicity study was conducted in Wistar rat (5/sex/dose) at concentrations of 50, 200, 400, 2000, and 5000 mg/kg bw. The test substance (Analogue 1) was applied to the intact dorsal skin, shorn on the previous day, and covered with an occlusive dressing for 24 hours. On removal, the treated skin sites were cleaned with water. Death occurred in 2/5 males at 2000 mg/kg bw and 5/5 males at 5000 mg/kg bw, and 5/5 females at 2000 mg/kg bw. Reddening, dark colour, incrustation, squamation and formation of scabs were observed from days 2-15. The main clinical signs included piloerection, decreased motility, decreased reactivity, poor respiration, no reflexes, spastic gait and laboured breathing. Clinical signs occurred 30 minutes after administration and were reversible within the post-treatment observation period. In animals which died during the observation period, a brownish-red content in the urinary bladder and discolouration of the liver was observed. Animals sacrificed at the end of the study showed no evidence of treatment-related gross findings. The LD_{50} was considered to be 2000 mg/kg bw for males and 400 mg/kg bw < LD_{50} < 2000 mg/kg bw for females. The test substance was considered to exhibit low-moderate acute dermal toxicity in rat. This value is similar to the acute oral LD_{50} of 550 mg/kg bw for females in the acute oral toxicity test in rat conducted with the notified chemical and further confirms that this is an appropriate analogue.

An acute inhalation toxicity study was performed in Wistar rats (5/sex/concentration). Animals were exposed head-/nose-only to the analogue aerosols at nominal concentrations of 1000, 5000, 20 000 or 50 000 mg/m^3 for 4 hours an observed for up to 14 days. The average analytical concentrations were 118.5, 586.4, 2007.6 and 3550.7 mg/m^3, respectively (approximately 0.1, 0.6, 2 and 3.6 mg/L). All of the particles were in the respirable range (< 3 μm). One death occurred in the highest exposure group and there were no deaths at the lower concentrations. The LC50 was found to be greater than 3.6 mg/L which corresponds to moderate acute inhalation toxicity in rat.

Irritation.
An acute dermal irritation study was performed on the notified chemical using the EpiDerm skin irritation assay. Toxicity, as a measure of cell viability, was evaluated for the various tissues at an optical density (OD) of 570 nm. The assay was considered to be acceptable if the positive control, Sodium Lauryl Sulfate (SLS) had a mean tissue viability (MTV) of ≤ 20% (reported MTV = 3.27%); the mean OD_{570} value of the negative control, Calcium and Magnesium Free Dulbecco's Phosphate Buffered Saline (CMF-DPBS), tissues was ≥ 1.000 and < 2.5000 (reported Mean OD_{570} = 2.042); and if the standard deviation (SD) calculated from the individual percent tissue viabilities of the three identically treated replicates of the negative or positive control were < 18%. The standard deviation calculated from individual percent tissue viabilities of the three identically treated replicates was < 18% for the positive control and negative control. Since the acceptance criteria were met, the assay was considered valid. A test substance is predicted to be an irritant if the mean relative viability of the three treated tissues is less than or equal to 50% of the mean viability of the negative control. The test substance was not observed to directly reduce MTT in the absence of viable cells, and the mean relative viability was found to be 3.26%. Based upon the results of this assay, the test substance was predicted to be irritating to skin.

In an *in vitro* bovine corneal opacity and permeability (BCOP) test the notified chemical was considered to be irritating to eyes.

Sensitisation.
A skin sensitization test was conducted on the notified chemical using the local lymph node assay (LLNA) in CBA mice. Groups of mice (5 females/dose) were treated with the test substance at 10, 25, and 50 % (w/v) in acetone/olive oil (4:1 v/v). The mice were treated by daily application of 25 μL of the appropriate concentration of the test substance to the dorsal surface of each ear for three consecutive days (Days 1, 2, 3). A further group of four mice received the vehicle alone in the same manner. On Day 6, all mice were injected via the tail vein with

250 µL of PBS containing ^{3}H-methyl thymidine giving a total of 19.9 µCi to each mouse. Five hours later, all mice were euthanized and the draining auricular lymph nodes were excised and pooled per animal. For the main test, no mortality occurred and no clinical signs of systemic toxicity were observed. Body weights and body weight gain of animals remained comparable to the control animals. All auricular lymph nodes of the treated and control group animals were considered normal in size. No macroscopic abnormalities of the surrounding area were noted for any of the animals. The mean DPM/animal values for animals treated with 10, 25 and 50% were 837, 709 and 980, respectively. The mean DPM/animal value for the vehicle control group was 452 DPM. The SI values calculated for animals treated with 10, 25 and 50% were 1.9, 1.6 and 2.2, respectively. As no group elicited an SI ≥ 3 when tested up to 50%, it was concluded that the test substance was not a sensitizer. The positive control, CP indicated that the assay was an appropriate model for testing sensitivity.

Repeated dose toxicity.
A 90-day repeated dose feeding study was conducted on Analogue 1 in Wistar rats. Animals were treated daily with an oral dose of 0, 27.4, 136.8 or 787.6 mg/kg bw/day for males and 0, 35.2, 178.5 and 894.6 mg/kg bw/day for females (0, 400, 2000 or 10 000 ppm, respectively). Additional groups of 10 males and 10 females were treated with 0 mg/kg bw/day or the highest dose tested in the same manner and then observed for a recovery period of 28 days. There were no mortalities. No effects were observed on the appearance and general behavior of the males at ≤ 2000 ppm, or of the females at ≤ 10000 ppm. Decreased body weight gain and emaciation were noted following 10 000 ppm in 5/20 males at Weeks 11 and 12. Decreased body weight gain was observed in mid-dose males (6-8% less than controls) and both sexes at 10000 ppm. Increased cholesterol concentrations observed in high-dose male and female rats were considered a consequence of hepatic fat metabolism that was reversible on the cessation of treatment. Increased relative liver weights in high-dose male and female rats were regarded as an adaptive effect resulting from impaired fat metabolism. Increased protein in the urine, an indication of tubule toxicity in the kidney and increased incidences of basophilic regenerated tubuli in the renal cortex were noted in the high-dose group of male rats and were considered to be treatment-related. Effects in the kidneys, i.e., basophilic tubuli were seen at the highest dose tested and affected 1/10 animals at a Grade 1 level, 3/10 at a Grade 2 level and 5/10 at a Grade 3 level. Although effects were also seen in the controls (3/10 animals), the severity was minimal (Grade 1). During the recovery phase, the incidence of basophilic tubuli effects in males was seen in 6/10 controls at a Grade 1 (minimal) level and 1/10 at a Grade 2 level. At the highest dose tested, the recovery animals showed 8/10 animals affected at the Grade 1 (minimal) level and 1/10 at a Grade 2 level, indicating that the effect on the kidneys was reversible (please see Table 8.2.2.3). Assessments of low-dose males and females revealed no apparent exposure-related adverse effects.

Several findings in clinical chemistry parameters and haematology assessments were reported, but were not considered to have been indicators of treatment-related adverse effects. Based on decreased body weight gain and emaciation in males, liver effects in both sexes and kidney effects in males, the LOAEL was considered to be greater than 787.6 mg/kg bw/day and the NOAEL was considered to be 136.8 mg/kg bw/day. Based on the severity of the kidney effects in males, it was concluded that the test substance exhibited moderate subchronic toxicity in rat.

Mutagenicity/Genotoxicity.
A bacterial reverse mutation assay (Ames test) was conducted on the notified chemical according to the plate incorporation method. A preliminary cytotoxicity test was performed at concentrations of 25-5000 µg/plate in order to determine the appropriate concentrations for the main study. The main assay was performed at concentrations of 50, 100, 250, 500, 1000, 2500 and 5000 µg/plate. Precipitates were not observed in any strain either with or without metabolic activation. Cytotoxicity (reduction in the background lawn and/or mean number of revertant colonies) was observed at ≥ 1000 µg/plate in strain TA1537 both with and without S9 (preliminary test only) and TA98 with S9 in the main test, and at ≥2500 µg/plate in TA98 without S9, TA100, TA1535 and WP2uvrA with and without S9, TA98 with S9 in the preliminary test only, and TA1537 with and without S9 in the main assay. Mean increases in the number of revertant colonies indicative of a positive response were not observed either with or without S9. Appropriate reference mutagens were used as positive controls and showed a distinct increase of induced revertant colonies, confirming the sensitivity of the test system and the activity of the S9 fraction. Based on this the test substance was considered to be negative for mutagenic activity both with and without metabolic activation.

An *in vivo* bone marrow micronucleus test was conducted in mice (Crl:CD1) on the notified chemical. Animals (6/sex/dose) were administered the test substance once daily by gavage for three consecutive days at dose levels of 75, 150 or 300 mg/kg bw/day. The negative control and positive control animals each received deionized water or cyclophosphamide, respectively, once daily for 3 consecutive days by gavage. Bone marrow was harvested from up to 5 mice per sex per group. The ratio of polychromatic erythrocytes (PCEs) to

normochromatic erythrocytes (NCEs) was determined by counting the number of PCEs observed while scoring 2000 erythrocytes per animal. There were no mortalities. Test substance-related clinical observations on study days 2 and 3 included dermal atonia, decreased defecation, small faeces, laboured respiration, gasping, pale extremities, swollen abdominal area, and/or yellow material on the ventral trunk. Body weight losses were noted in all treated male groups and in the 75 and 300 mg/kg bw/day group of females. A mean body weight loss was noted in the 150 mg/kg/day group females, but was not statistically significant. The effects on body weight gain resulted in 10.4%-16.3% lower mean body weights across the male groups (statistically significant at 150 and 300 mg/kg/day) and 10.2%-12.1% lower mean body weights across the female groups (statistically significant at 75 and 300 mg/kg/day) at the end of the study when compared to the control group. Slightly lower food consumption was noted in all treated male and female groups, but was considered statistically significant only for females at 300 mg/kg/day. The test substance did not produce and increase in the mean number of micronucleated polychromatic erythrocytes (%MN-PCEs) compared to the negative control group. No bone marrow cytotoxicity (decreases in the ration of polychromatic to total erythrocytes, PCE:TE ratio) was noted in any test substance-treated group. The group mean vales for both %MN-PCEs and PCE:TE rations for the negative and positive controls were within the respective historical control ranges. As a result the test substance was considered to be non-clastogenic.

The ability of Analogue 1 to induce structural chromosomal aberrations *in vitro* was investigated using Chinese hamster ovary cells both with and without metabolic activation (S9). In the main experiment, the following concentrations of test substance were used 0, 10, 40, and 160 µg/mL, without S9, and 0, 7.2, 36 and 180 µg/mL with S9. The test substance induced cytotoxic effects in cells exposed to the highest concentrations both with and without S9 at the earliest harvest time of 8 hours. The mitotic indices were markedly reduced to 66.7 and 43.2%, respectively, relative to solvent controls. No significant cytotoxic effects were seen for the harvest times of 24 and 30 hours (-S9). A statistically significant increase of the number of cells with aberrations was calculated for cells exposed to 180 µg/mL (with metabolic activation), harvested at 8 hours. However, the absolute number of cells with aberrations (3.5%) was within the normal range as compared to the values for other solvent controls within this study and other historical data. Therefore this statistically significant increase was considered to be caused by the unusually low number of cells with aberrations in the corresponding solvent control group and was thus considered not to be biologically relevant. No other statistically significant or biologically relevant increases of number of cells with aberrations were detected 24 or 30 hours after treatment in the presence of S9. The positive controls mitomycin C and cyclophosphamide induced clear clastogenic effects and demonstrated the sensitivity of the test system. The test substance was considered to be non-clastogenic.

Developmental/Reproductive toxicity.
A developmental toxicity test was performed in Wistar rat on Analogue 1. Pregnant Wistar rats (25 females/dose) were administered the test substance by gavage at doses of 50, 150 or 450 mg/kg bw/day on days 6-15 of gestation. Animals were observed until gestation day 21. Maternal effects included reduced food consumption in mid- and high-dose females and clinical signs of toxicity in high-dose females included ruffled fur, ventral recumbency, dyspnoea, apathy, abdominal hair loss and comatose state. Blood was found in the uterus in one control and two low-dose females. The significant developmental effects observed at the high dose included increased mean foetal body weight, increased post-implantation loss and skeletal malformations (non-ossified cervical vertebra, incompletely ossified sternebra and non-ossified metatarsals). No treatment-related developmental effects were noted regarding mean number of corpora lutea, implantations, pup sex ratio, pre-implantation loss, number of foetuses or mean number of live foetuses. The LOAEL for maternal toxicity was considered to be equal to 450 mg/kg bw/day based on adverse clinical signs in dams and effects on mean body weight and the NOAEL for maternal toxicity was found to be equal to 150 mg/kg bw/day. The LOAEL for developmental toxicity was considered to be equal to 450 mg/kg bw/day based on post-implantation loss and skeletal malformations in foetuses which was the same level where maternal toxicity was seen and therefore differentiation between maternal toxicity and developmental effects are considered inconclusive. The NOAEL for developmental toxicity was found to be equal to 150 mg/kg bw/day. Therefore this corresponds to low maternal toxicity in rat. Although the hazard classification for developmental toxicity was not determined in this study, Health Canada concluded that the test substance was a developmental toxicant.

A second developmental toxicity test was performed in Chinchilla rabbits (16 females/dose). Rabbits were administered the test substance via gavage at 100, 300 or 1000 mg/kg bw/day on gestation days 6-18. Animals were observed until gestation day 28. Mortality was observed in the low-, mid- and high-dose animals (3, 1 and 1 animal, respectively). The cause of death in two low-dose animals was attributed to intubation error, but the cause of death in all others was undetermined. Clinical signs of toxicity noted in the high-dose females that died included slight dyspnoea and ventral recumbency; dyspnoea was also observed in a surviving female. No abnormal clinical signs were noted in controls or animals treated with 100 or 300 mg/kg bw/day. High-dose

animals experienced decreased food consumption (21% lower than controls) and decreased body weight gain (> 50% less than controls) during the dosing period and increased food consumption and weight gain during the recovery period. Two mid-dose animals experienced total resorptions, but this effect was considered incidental by the study authors due to a lack of post-implantation loss at the higher dose. Histopathological findings included discoloured foci and nodules or crateriform retractions in the mucosa of the fundus, forestomach or stomach. These findings were considered incidental as they commonly occur in rabbits of similar strain and age. Except for two runts in the control and 300 mg/kg bw/day groups, external examination showed no abnormal findings in the 100 or 1000 mg/kg bw/day groups. No treatment-related effects for corpora lutea, pre-implantation loss, post-implantation loss, number of foetuses, mean numbers of live foetuses, mean fetal body weight, external pup examination or pup sex rations were observed. Skeletal malformations (incomplete ossification) were sporadic at the low and mid-doses, but were consistently significant at the high dose. The LOAEL for maternal toxicity was equal to 1000 mg/kg bw/day based on mortality, reduced food consumption, body weight gain and clinical signs of toxicity; the NOAEL for maternal toxicity was considered to be equal to 300 mg/kg bw/day. The LOAEL for developmental toxicity was considered to be equal to 1000 mg/kg bw/day based on incomplete ossification of limbs, which was the same level where maternal toxicity was seen and therefore differentiation between maternal toxicity and developmental effects are considered inconclusive. The NOAEL for developmental toxicity was found to be equal to 300 mg/kg bw/day. Therefore this corresponds to low maternal toxicity in rabbit. Although the hazard classification for developmental toxicity was not determined, Health Canada concluded that the test substance was not a developmental toxicant.

Health hazard classification

Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Acute Toxicity, Oral (Category 4)	H302 – Harmful if swallowed
Acute Toxicity, Dermal (Category 4)	H312 – Harmful in contact with skin
Skin Corrosion/Irritation (Category 2)	H315 – Causes skin irritation
Serious Eye Damage/Eye Irritation (Category 2)	H319 – Causes eye irritation

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrases:

R22: Harmful if swallowed
R21: Harmful in contact with skin
R38: Irritating to skin
R36: Irritating to eyes

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 harmful if swallowed or in contact with the skin, and irritating to the eyes and skin. The potential for acute inhalation toxicity cannot be ruled out. Therefore, caution should be exercised when handling the notified chemical and during reformulation processes.

Reformulation

Dermal, ocular and potentially inhalation exposure to the notified chemical at up to 100% concentration may occur during reformulation. The stated use by the notifier of PPE such as coveralls, eye protection, impervious gloves and respiratory protection (as appropriate) and engineering controls including automated/enclosed processes and local exhaust ventilation should minimise the risk for workers.

Provided that control measures stated by the notifier are in place to minimise worker exposure, including the use of automated processes and PPE, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

End-use
Workers involved in industrial settings where there is use of cleaning products containing the notified chemical may be exposed to the notified chemical at concentrations up to 100%. Where appropriate controls include appropriate ventilation (such as operating in a well-ventilated area, use of local exhaust ventilation and/or other respiratory protection as appropriate) as well as use of PPE, the risk to these workers is expected to be of a similar or lesser extent than that experienced by workers involved in the reformulation of the notified chemical into end-use products.

Workers involved in professions where the services provided involve the use of cleaning products containing the notified chemical may be exposed to the notified chemical at concentrations up to 10%. If PPE is used, the risk to these workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical (for details of the public health risk assessment, see Section 6.3.2).

6.3.2. Public Health
Household cleaning products containing the notified chemical at ≤ 10% concentration will be available to the public. The main route of exposure is expected to be dermal with some potential for accidental ocular or oral exposure.

Local effects
The notified chemical is not expected to be a skin sensitiser based on animal studies. The notified chemical is irritating to the skin and eyes. The notified chemical is not expected to have significant skin and eye irritating effects at the proposed use concentration (≤ 10%).

Systemic effects
Members of the public may experience repeated exposure to the notified chemical through the use of household products (containing the notified chemical at ≤ 10% concentration).

The repeat dose toxicity potential was estimated by calculation of the margin of exposure (MoE) of the notified chemical using the worst case exposure scenario from use of multiple products of 0.5861 mg/kg bw/day (see Section 6.1.2) and the NOAEL of 136.8 mg/kg bw/day, as determined in a 90-day repeated dose toxicity study on an analogous chemical. Using the abovementioned NOAEL, a MoE of 233 was estimated. A MoE value ≥ 100 is considered acceptable to account for intra- and inter-species differences, and to account for long-term exposure; therefore, the MoE is considered to be acceptable.

Overall, based on the information available, the risk to the public associated with the use of the notified chemical at up to 10% concentration in household cleaning products 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 neat as a finished product, or for reformulation into finished industrial cleaning products, domestic cleaning products, or industrial metal cleaners and metal working fluids. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the notified chemical is expected to be collected with adsorbents for disposal to licensed waste management facilities in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified chemical to the environment from this process is not expected. The reformulation process will be followed by automated filling of the finished cleaning products and metal cleaners and metal working fluids into containers suitable for distribution and end-use. The notified chemical may also be repackaged for distribution and end use without further reformulation. Wastes containing the notified chemical generated from reformulation and repackaging processes include spilt materials and equipment wash water. These are expected to be collected for disposal by licensed waste management services in accordance with local government regulations. Empty import containers are also expected to be recycled or disposed of through licensed waste management services.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be used in industrial cleaning products, domestic cleaning products, and industrial metal cleaners and metalworking fluids. During use, the notified chemical may also be released to the environment as accidental spills and leaks. These are expected to be collected with adsorbents for disposal by licensed waste management services in the case of industrial applications, or disposed of to landfill in the case of domestic applications.

Industrial cleaning

The notified chemical in industrial cleaning products will be used for hard surface cleaning, cleaning oilfield equipment, industrial and commercial automotive cleaning, and industrial laundry pre-soaks. It is estimated by the notifier that up to 80% of the import volume of the notified chemical (or up to 400,000 kg) will be used in industrial cleaning products. For hard surface and equipment cleaning, the majority of the cleaning products containing the notified chemical will be absorbed onto rags, which will be collected for disposal to landfill following use in accordance with local government regulations. For industrial and commercial automotive cleaning, it is estimated by the notifier that < 1% of the total import volume of the notified chemical (or less than 5,000 kg) will be used. Automotive cleaning products containing the notified chemical will be used in industrial and commercial facilities fitted with engineering controls to capture wash water. Wash water containing the notified chemical will be collected and treated on-site before eventual disposal to sewer, or collected for disposal by licensed waste management services. For industrial laundry applications, cleaning products and wash water containing the notified chemical will be collected for disposal by licensed waste management services.

Domestic cleaning

The notified chemical in domestic cleaning products will be used in a variety of applications including household cleaning products and car care products. It is estimated by the notifier that < 15% of the import volume of the notified chemical (or less than 75,000 kg) will be used in domestic cleaning products, and < 1% of the import volume (or less than 5,000 kg) will be used in car care products. When cleaning is conducted using rags or sponges, the majority of the cleaning products containing the notified chemical will be absorbed onto the rags or sponges. These will be disposed of to landfill as domestic waste, or rinsed and reused. Where rinsing of cleaning rags and sponges occur, the majority of the notified chemical will be released to sewer. For car cleaning applications, cleaning products and wash water containing the notified chemical is expected to be released to stormwater drains.

Industrial metal cleaners and metalworking fluids

The notified chemical in industrial metal cleaners and metalworking fluids will be used by professional users in industrial settings only. It is estimated by the notifier that up to 5% of the import volume of the notified chemical (or up to 25,000 kg) will be used in metal cleaners and metalworking fluids. Metal cleaners and metalworking fluids will be used in enclosed systems, with spent fluids collected for disposal by licensed waste management services.

RELEASE OF CHEMICAL FROM DISPOSAL

Industrial cleaning

The majority of the notified chemical in industrial cleaning products will either be absorbed onto rags or collected as liquid wastes. A small proportion of the notified chemical may remain in end-use containers once cleaning products are used up. Wastes and container residues of the notified chemical are expected to be collected for disposal by licensed waste management services.

Domestic cleaning

A small proportion of the notified chemical may remain in end-use containers once domestic cleaning products are used up. Wastes and residues of the notified chemical in empty containers are likely either to share the fate of the container and be disposed of to landfill, or to be released to sewer when containers are rinsed before recycling through an approved waste management facility.

Industrial metal cleaners and metalworking fluids

The majority of the notified chemical in metal cleaners and metalworking fluids will be collected as spent fluids following use. A small proportion of the notified chemical may remain in containers once cleaning fluids are used up. All wastes and container residues of the notified chemical are expected to be collected for disposal by licensed waste management services.

7.1.2. Environmental Fate

Following its use in industrial cleaning products and metal cleaners and metalworking fluids, the majority of the notified chemical is expected to be collected for treatment and disposal by licensed waste management services. During waste treatment, the majority of the notified chemical is expected to partition to sludge and sediment under environmental pH, based on its surface activity. Based on the results of a ready biodegradability study, the notified chemical is considered to be readily biodegradable (63.93% in 28 days). For details of the environmental fate study, please refer to Appendix C. Therefore, very little of the notified chemical is expected to partition to supernatant waters. Solid wastes and sludge and sediment containing the notified chemical are expected to be disposed of to landfill, or applied to land when sewage sludge is used for soil remediation. The notified chemical in landfill and in soil and sludge is expected to degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

Following use in domestic cleaning products and car care products, the majority of the notified chemical is expected to enter the sewer system or stormwater drains, before release to surface waters nationwide. The notified chemical is also expected to enter landfill as collected wastes and residues. Release of the notified chemical to surface water is unlikely to occur as partitioning to sludge and sediment is expected. The notified chemical is not expected to be bioaccumulative based on its surface activity and ready biodegradability. Therefore, in surface waters and in landfill, the notified chemical is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

Predicted Environmental Concentration from industrial and commercial automotive cleaning applications

The predicted environmental concentration (PEC) has been calculated based on the volume of the notified chemical in industrial and commercial automotive cleaning products. The PEC has been calculated using a conservative scenario where the total annual import volume expected to be used in industrial and commercial automotive cleaning products (< 1%, or less than 5,000 kg) is released to sewer systems nationwide. As industrial and commercial automotive cleaning is to occur at professional facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume. It is conservatively assumed that none of the notified chemical will be removed during sewage treatment plant (STP) processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	500,000	kg/year
Proportion expected to be released to sewer	1%	
Annual quantity of chemical released to sewer	5,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	19.23	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	3.029	µg/L
PEC - Ocean:	0.303	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 3.029 µg/L may potentially result in a soil concentration of approximately 20.19 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 101.0 µg/kg and 201.9 µg/kg, respectively.

Predicted Environmental Concentration from domestic cleaning (excluding car cleaning applications)

The predicted environmental concentration (PEC) has been calculated based on the volume of the notified chemical in domestic cleaning products (not including car care applications). The PEC has been calculated using a conservative scenario where the total annual import volume expected to be used in domestic cleaning products

(< 15%, or less than 75,000 kg) is released to sewer systems nationwide. The PEC has been calculated assuming 63% removal of the notified chemical from influent during sewage treatment plant (STP) processes through biodegradation.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	500,000	kg/year
Proportion expected to be released to sewer	15%	
Annual quantity of chemical released to sewer	75,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	205.48	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	**63%**	**mitigation**
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	16.811	µg/L
PEC - Ocean:	1.681	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 16.81 µg/L may potentially result in a soil concentration of approximately 112.1 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 560.3 µg/kg and 1.121 mg/kg, respectively.

Predicted Environmental Concentration from domestic car cleaning applications
It is estimated by the notifier that < 1% of the total annual import volume of the notified chemical (or less than 5,000 kg) is expected to be used in domestic car care products. The PEC has been calculated assuming 100% release to stormwater drains nationwide. 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 5,000 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 20 µg/L. This result reflects a worst case scenario upper limit, as in reality releases of the notified chemical will be distributed over multiple regions and it will be further diluted if it reaches the ocean.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 8.0 mg/L	Potentially toxic to fish
Daphnia Toxicity	48 h EC50 = 2.8 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	96 h EC50 > 9.0 mg/L	Potentially toxic to algae

Based on the above ecotoxicological endpoints for the notified chemical, it is expected to be toxic to aquatic invertebrates, and is potentially toxic to fish and algae. 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 2; Toxic to aquatic life'. Based on the ready biodegradability of the notified chemical and its low potential to bioaccumulate, it is not formally classified under the GHS for chronic toxicity.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the most sensitive endpoint for daphnia. A safety factor of 100 was used given acute endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (*Daphnia*, 48 h)	2.8	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	28	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) for the notified chemical used in industrial cleaning products (excluding automotive cleaning) and metal cleaners and metalworking fluids has not been calculated, as significant release to the aquatic compartment is not expected. Therefore, the notified chemical is not expected to be released to the aquatic compartment at ecotoxicologically significant concentrations from these uses.

The Risk Quotients for the notified chemical used in industrial and commercial automotive cleaning products, domestic cleaning products, and domestic car care products have been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Industrial and commercial automotive cleaning applications			
Q – River	4.252	28	**0.152**
Q – Ocean	0.425	28	**0.015**
Domestic cleaning (excluding car cleaning applications)			
Q – River	16.811	28	**0.600**
Q – Ocean	1.681	28	**0.060**
Domestic car cleaning applications			
Q – River	20	28	**0.714**
Q – Ocean	2	28	**0.071**

The Risk Quotient for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters. Based on its annual importation quantities the notified chemical is expected to be used in industrial and commercial automotive cleaning products, domestic cleaning products, and domestic car care products. The notified chemical is considered readily biodegradable, and hence is not expected to be bioaccumulative. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in domestic cleaning products and domestic car cleaning applications, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Freezing Point -11.2 °C

Method	OECD TG 102 Melting Point/Melting Range.
Remarks	Determined based on observed solidification
Test Facility	Harlan (2014a)

Boiling Point 293 °C at 102.1 kPa (decomposes)

Method	OECD TG 103 Boiling Point.
Remarks	Determined using a differential scanning calorimeter
Test Facility	Harlan (2014a)

Density 893 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids.
Remarks	Pycnometer method
Test Facility	Harlan (2014a)

Vapour Pressure 2.4×10^{-4} kPa at 25 °C

Method	OECD TG 104 Water Solubility. EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	Vapour pressure balance method
Test Facility	Harlan (2014b)

Water Solubility 1.25 g/L at 20 °C

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

Partition Coefficient (n-octanol/water) log Pow = 3.17 at 30 °C

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

Surface Tension 42.2 mN/m at 20 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions. EC Council Regulation No 440/2008 A.5 Surface Tension.
Remarks	Concentration: 1.0 g/L in water
Test Facility	Harlan (2014a)

Flash Point 146 ± 2 °C at 101.3 kPa

Method	EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks	Closed cup method
Test Facility	Harlan (2014c)

Autoignition Temperature 240 °C

Method	ASTM E659 - Standard Test Method for Autoignition Temperature of Liquid Chemicals
Remarks	Open flask used. The more volatile vapours vented out first which may minimise the probability of these vapours autoigniting in the flask.
Test Facility	Fauske (2013)

Explosive Properties Predicted negative

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	Based on chemical structure
Test Facility	Harlan (2014a)

Oxidizing Properties Predicted negative

Method	EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids).
Remarks	Based on chemical structure
Test Facility	Harlan (2014a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – eye (in vitro)

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage
Vehicle	None
Remarks - Method	No significant protocol deviations. Concurrent negative (deionised water) and positive (ethanol) controls were used.

RESULTS

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	0.0	0.000	0.0
*Test substance**	8.5 (2.0)	1.484 (0.479)	30.8
*Positive control**	28.7 (4.5)	0.899 (0.241)	42.2

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Remarks - Results	The test substance may be classified as a moderate irritant (25.1 ≤ IVIS ≤ 55) based on the classification system established by Sina et al (1995) which was referred to by the study authors. However, the study authors stated that the specific classification ranges established by Sina et al may not be applicable to all classes of materials. As the IVIS value for the test substance was > 3 and ≤ 55, no prediction on classification can be made under the GHS (United Nations, 2009). The positive and negative controls gave satisfactory results, confirming the validities of the test systems.
CONCLUSION	The notified chemical was considered to be a moderate eye irritant under the conditions of the test.
TEST FACILITY	IIVS (2014)

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