File No: STD/1489

December 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

NYCOBASE 8311

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

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

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

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/1489	Cintox Australia Pty Ltd	NYCOBASE 8311	No	≤ 200 tonnes per annum	A component of lubricants

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

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

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

Environmental risk assessment
On the basis of the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

CONTROL MEASURES

Occupational Health and Safety

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

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

  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.

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

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

No additional secondary notification conditions are stipulated.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
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, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints with the exception of water solubility and all human health endpoints with the exceptions of acute oral toxicity and induction of point mutations.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NYCOBASE 8311

MOLECULAR WEIGHT
< 1,000 Da

ANALYTICAL DATA
Reference NMR, IR, GC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 96%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear liquid

Property	Value	Data Source/Justification
Pour point	-39 °C	TDS
Boiling Point	> 430 °C at 101.3 kPa	Calculated – EPISuite (v4.10); US EPA, 2012
Density	937 kg/m^3 at 20 °C	TDS
Vapour Pressure	4.05 × 10^{-8} kPa at 25 °C	Calculated – EPISuite (v4.10); US EPA, 2012
Water Solubility	4.1 × 10^{-4} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities, however, hydrolysis is expected to be slow under environmental conditions (pH 4 – 9).

Partition Coefficient (n-octanol/water)	log Pow > 7.7 at 25 °C	Calculated (KOWWIN v1.68; US EPA, 2012).
Adsorption/Desorption	log K_{oc} > 5.1 at 25 °C	Calculated (KOWWIN v2.00; US EPA, 20112).
Dissociation Constant	Not determined	Does not contain dissociable functionalities.
Flash Point	> 268 °C	TDS
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use, based on the flash point.
Explosive Properties	Not determined	Not expected to be explosive as the structural formula contains no explosophores.
Oxidising Properties	Not determined	Not expected to have oxidising properties based on the structure.

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

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

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured with in Australia. The notified chemical will be imported into Australia as a neat (> 96% purity) liquid.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	50 – 100	50 – 100	50 – 100	50 – 100	50 – 200

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Australia in 26,000 L isotainers, 205 L drums or 1 – 20 L cans. The neat notified chemical will then be transported by road or rail to reformulators warehouses where end use lubricants containing up to 80% notified chemical will be packaged in 1 – 205 L containers for transportation to end use customers.

USE
The notified chemical will be used as a component of engine lubricants at concentrations up to 80%. The lubricants containing the notified chemical will be used by both industry and the public.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia.

Reformulation
At customer blending sites, the notified chemical (at > 96%) will be transferred from the import containers to on-site storage tanks. From the storage tanks the notified chemical will be pumped to the blending tank through computer controlled fixed lines. The notified chemical will then be blended with other components to form the finished lubricant where the maximum concentration of the notified chemical will be 80%. Samples may be taken during the blending process for quality control testing. The finished lubricant will then be pumped to

storage tanks prior to being packaged on automated filling lines into 205 L drums down to 1 L containers. Reformulation facilities are expected to be fully automated, well ventilated and use closed systems.

End use
Lubricants containing the notified chemical at concentrations up to 80% will be used in automotive manufacturing facilities, automotive repair facilities and by professionals and the public in a range of equipment with petrol powered engines such as lawnmowers and chainsaws. End-users are expected to open the containers and manually transfer the finished lubricant into the engine. In original equipment manufacture and other high use situations the finished lubricant may be pumped from the drums into the engine oil reservoir.

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)*
Transport and warehousing	1 – 2	12
Reformulation	8	24
Quality assurance	1	24
Maintenance	1	24
End use	8	200

EXPOSURE DETAILS

Transport and storage
It is anticipated that waterside workers, transport drivers and warehouse workers would only be exposed to the material in the event of an accident.

Reformulation
Dermal and ocular exposure to the notified chemical (> 96% concentration) is possible when plant operators are connecting and disconnecting pump lines to storage tanks or blending vessels. It is expected that negligible exposure will occur during the fully automatic and closed blending process. The opportunity also exists for dermal exposure (> 96% concentration) when cleaning up spills or leaks and during maintenance of the blend vessel. Workers involved in the blending process are expected to wear gloves, eye protection and protective clothing to further minimise exposure.

Negligible exposure is expected during transfer of the finished lubricant containing the notified chemical at > 96 % concentration to packaging as this will be carried out using automated processes. Inhalation exposure is expected to be negligible given the predicted very low vapour pressure of the notified chemical (4.05×10^{-8} kPa at 25 °C). In addition, blending and packaging facilities are expected to be well ventilated.

Sampling
At reformulation facilities samples will be taken from blending vessels for quality assurance testing. Dermal exposure to the notified chemical (at > 96%) may occur during sampling. To minimise exposure the plant operator is expected to wear gloves, eye protection and protective clothing.

End use
There is potential for dermal and ocular exposure to the notified chemical at concentrations up to 80% by workers at automotive manufacturing facilities and automotive repair facilities and by professionals using a range of equipment with petrol powered engines such as lawnmowers and chainsaws. Exposure may be minimised by the use of gloves, goggles and protective clothing.

6.1.2. Public Exposure
Dermal and ocular exposure to the notified chemical (up to 80% concentration) by the public may occur during the use of or changing of the engine oil in a range of equipment with petrol powered engines such as

lawnmowers and chainsaws. PPE is not expected to be worn by the public although the frequency of exposure is expected to be low.

6.2. Human Health Effects Assessment

There is no toxicological data available on the notified chemical. The results from toxicological investigations conducted on analogue chemicals are summarised in the following table. For full details of the studies with analogue 1, refer to Appendix B.

Endpoint	*Test substance*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Analogue 1	LD50 > 5,000 mg/kg bw; low toxicity
Rat, acute oral toxicity	Analogue 2	LD50 > 5,000 mg/kg bw; low toxicity
Rat, acute oral toxicity	Analogue 3	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute oral toxicity	Analogue 3	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute oral toxicity	Analogue 3	LD50 > 5,000 mg/kg bw; low toxicity
Rat, acute oral toxicity	Analogue 4	LD50 > 2,000 mg/kg bw; low toxicity
Guinea pig, skin sensitisation	Analogue 6	no evidence of sensitisation
Guinea pig, skin sensitisation	Analogue 7	no evidence of sensitisation
Human, skin sensitisation – RIPT (5%)	Analogue 8	no evidence of sensitisation
Human, skin sensitisation – RIPT (1.7%)	Analogue 9	no evidence of sensitisation
Human, skin sensitisation – RIPT (55%)	Analogue 10	no evidence of sensitisation
Rat, repeat dose dermal toxicity – 28 days.	Analogue 2	NOAEL = 500 mg/kg bw/day
Rat, repeat dose oral toxicity – 28 days.	Analogue 4	NOAEL = 300 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	Analogue 1	non mutagenic
Mutagenicity – bacterial reverse mutation	Analogue 2	non mutagenic
Mutagenicity – bacterial reverse mutation	Analogue 3	non mutagenic
Mutagenicity – bacterial reverse mutation	Analogue 4	non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration Test	Analogue 2	non genotoxic
Genotoxicity – in vitro Mammalian Chromosome Aberration Test	Analogue 4	non genotoxic
Genotoxicity – in vivo mammalian erythrocyte micronucleus test	Analogue 4	non genotoxic
Rat, reproductive and developmental toxicity (dermal)	Analogue 2	NOAEL (developmental) > 2,000 mg/kg bw/day NOAEL (maternal)* > 2,000 mg/kg bw/day

* This NOAEL excludes local effects.

Toxicokinetics, metabolism and distribution.
Based on the lipophilicity of the notified chemical (water solubility 4.1×10^{-4} g/L at 20 °C; log Pow > 7.7 at 25°C) dermal absorption is expected to be low.

The notified chemical is a fatty acid ester and as such may enhance the dermal absorption of chemicals that it is mixed with, although due to the saturation of the fatty acids and the notified chemical's moderately high molecular weight such effects are expected to be reduced (Trommer et al., 2006).

Acute toxicity.
Analogue 1 was tested in an acute oral toxicity study in rats with no unscheduled deaths, clinical signs or macroscopic findings observed and the LD50 being > 5,000 mg/kg bw (Phycher, 2010).

Analogue 2 was administered to rats by a single oral gavage with no adverse treatment related effects observed and the LD50 therefore being > 5,000 mg/kg bw (HPV, 2010).

In three acute oral toxicity studies in rats analogue 3 was administrated at doses of 2,000 or 5,000 mg/kg bw/day with no mortality or adverse effects noted (HPV, 2010).

There was no mortality or systemic effects following the administration of analogue 4 in an acute oral toxicity study, with the LD50 being > 2,000 mg/kg bw (HPV, 2010).

Irritation and sensitisation.
In the repeated dose dermal toxicity study with analogue 2 (described below), local effects were observed at all the doses tested (HPV, 2010). The local effects seen in the repeated dose study with analogue 2 included erythema, skin sloughing and paleness of the skin, although no effects were observed in the first week of the study.

Analogue 5 produced only slight dermal irritation when applied to the skin of rats at doses up to 2,000 mg/kg bw/day for 13 weeks (CIR, 2012).

In sensitisation studies in guinea pigs analogues 6 and 7 showed no evidence of sensitisation at concentrations up to 50 and 100% respectively (CIR, 2012).

In three separate human repeated insult patch tests with analogues 8, 9 and 10 at concentrations of 5, 1.7 and 55%, respectively there was no evidence of either irritation or sensitisation.

There were no eye irritation studies provided for the notified chemical or any suitable analogue. The notified chemical contains no reactive functional groups or structural alerts and therefore the potential for eye irritation is expected to be low. However, the possibility that the notified chemical may be an eye irritant cannot entirely be ruled out with the available information.

Repeated dose toxicity.
Analogue 2 was applied to rats in a 28 day dermal toxicity study at doses up to 2,000 mg/kg bw/day (HPV, 2010). There were slight body weight decreases in both male and female rats at the highest dose of 2,000 mg/kg bw/day along with changes in haematological and clinical chemistry parameters, which were largely absent from the groups treated with lower doses. There were no microscopic changes observed in the organs; however, based on the changes in haematological and clinical chemistry parameters at the highest dose of to 2,000 mg/kg bw/day the NOAEL should be set at the lower dose of 500 mg/kg bw/day.

A 28 day oral toxicity study in rats was conducted with analogue 4 at concentrations up to 1,000 mg/kg bw/day (HPV, 2010). An increase in the liver weight with enlarged hepatocytes was observed in the highest dose group only. No other treatment related adverse effects were noted and therefore the NOAEL was set at a dose of 300 mg/kg bw/day.

Mutagenicity/Genotoxicity.
Analogue 1 was found to be non mutagenic using a bacterial reverse mutation test, both in the presence and absence of metabolic activation (Vivotecnia, 2010).

Analogues 2, 3 and 4 were non-mutagenic in bacterial reverse mutation assays and analogues 2 and 4 did not induce chromosomal aberrations in Chinese hamster ovary cells *in vitro* (HPV, 2010). In an *in vivo* mammalian erythrocyte micronucleus test, analogue 4 produced no dose related or statistically significant increases in micronucleated polychromatic erythrocytes in mice (HPV, 2010).

Toxicity for reproduction.
In a developmental toxicity study analogue 2 was dermally applied to approximately 10% of the body surface area of pregnant rats on gestation days 6 – 15 for at least 6 hours per day at doses up to 2,000 mg/kg bw/day (HPV, 2010). There were no adverse systemic effects on maternal toxicity, although local irritation was noted in the two highest doses. There were no adverse effects noted in the foetuses, foetal number or sex ratio at any of the doses tested. The NOAEL for analogue 2 for developmental effects was the highest dose tested at > 2,000 mg/kg bw/day while the NOAEL for maternal effects was set by the study authors as 200 mg/kg bw/day based only on the presence of local irritation at higher doses and therefore the NOAEL for systemic effects in the maternal animals would be > 2,000 mg/kg bw/day.

Health hazard classification
Based on the available information, the notified chemical is not recommended for classification 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

There is no toxicological data available for the notified chemical. However, the notified chemical has no structural alerts that suggest it may be hazardous to human health and toxicological data for analogous chemicals also indicate it would be of low toxicity. However, there was no available data on the eye irritation potential of the notified chemical or any suitable analogues and in the absence of such information suitable precautions should be taken when using or handling the notified chemical or products containing it due to the uncertainty around the hazard.

There is potential for dermal and ocular exposure of workers to the notified chemical at up to 100% concentration during reformulation and at up to 80% concentration during the manufacture, repair and use of automotive and petrol powered engines containing lubricants incorporating the notified chemical. Due to the expected low systemic hazard of the notified chemical and the potential for PPE to be used by workers to limit exposure to it, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

The public may be exposed to the notified chemical at concentrations up to 80% during the repair and use of automotive and petrol powered engines containing lubricants incorporating the notified chemical. Due to the expected low systemic hazard of the notified chemical and the expected low frequency of exposure, the notified chemical is not considered to pose an unreasonable risk to public health.

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, 200 kg/yr (200 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 20 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 1.4 tonnes/yr (= 200 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

The notified chemical is not readily biodegradable, however, it is expected to be biodegradable in the environment (63% biodegraded after 28 days). For the details of the environmental fate studies please refer to Appendix C. Most of the notified chemical will be either thermally decomposed during use, recycled or re-refined.

The notified chemical has very low water solubility at 4.1×10^{-4} g/L. With a high adsorption/desorption coefficient of log $K_{OC} > 5.1$, and high partition coefficient of log $P_{OW} \geq 7.7$, the notified chemical is expected to partition to organic matter and to sediments and soils in the environment, and is therefore considered highly immobile within a landfill environment. Notified chemical released to surface water is expected to partition to sediment based on its limited water solubility and high log Koc value. Therefore, the notified chemical is not expected to be significantly bioavailable. The notified chemical has a tendency to partition to organic phases as indicated by its n-octanol/water partition coefficient (log Pow ≥ 7.7), which indicates a potential to bioaccumulate. However, given the notified chemical is expected to be degradable, not significantly bioavailable and is not expected to be released to the aquatic environment, the notified chemical has limited potential for bioaccumulation.

Despite the presence of a hydrolysable functionality, the potential for hydrolysis is low due to poor water solubility of the notified chemical. However, a reasonable level of biotic degradation (63% in 28 days) has been detected. Therefore, the notified chemical is expected to quickly break down in either a landfill or aquatic environment to form water and oxides of carbon

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 1.4 tonnes/yr (= 200 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 1.4 tonnes 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 5.6 µg/L. This result reflects a worst-case scenario upper limit, as in reality releases of the notified chemical will be distributed over multiple areas. Moreover, the concentrations of the notified chemical 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. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish	LL50 (96 h) > 1,001mg/L (WAF)	Not harmful to fish up to the limit of solubility
Daphnia	LL50 (48 h) > 1,001 mg/L (WAF)	Not harmful to aquatic invertebrates up to the limit of solubility
Algae	LL50 (72 h) > 1,011 mg/L (WAF)	Not harmful to algae up to the limit of solubility

Water Accommodated Fraction (WAF)

Classification should be based only on toxic responses observed in the soluble range. The ecotoxicity endpoints for the notified chemical are much higher than its solubility limit. Hence, the notified chemical is not expected to be harmful to aquatic organisms at its solubility limit in the aquatic environment. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified chemical is not expected to be harmful to fish, invertebrates and algae on an acute or long term basis and is not formally classified under the GHS.

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) for the aquatic compartment has not been calculated since the notified chemical is not considered to be harmful up to the limit of its solubility in water.

7.3. Environmental Risk Assessment

The risk quotient (RQ = PEC/PNEC) has not been calculated. The notified chemical is not harmful up to its solubility limit. The notified chemical is not expected to persist in the environment due to its biodegradability. Therefore, based on the assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 4.07×10^{-4} g/L at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Column Elution Method
Test Facility	BfB (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Analogue 1

METHOD
- Species/Strain: Rat/Sprague Dawley
- Vehicle: Test substance administered as supplied.
- Remarks - Method: No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 females	5,000	0/3

- LD50: > 5,000 mg/kg bw
- Signs of Toxicity: There were no unscheduled deaths during the study. There were no observed adverse clinical signs.
- Effects in Organs: No adverse macroscopic findings were recorded at necroscopy.
- Remarks - Results: The body weights were within the range commonly recorded for this strain and age of rats.

CONCLUSION: Analogue 1 is of low toxicity via the oral route.

TEST FACILITY: Phycher (2010)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE: Analogue 1

METHOD: OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure and Pre incubation procedure

- Species/Strain: *S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
  E. coli: WP2 (pKM101)
- Metabolic Activation System: S9 rat liver microsome fraction induced with Aroclor
- Concentration Range in Main Test: a) With metabolic activation: up to 5 µL/plate
  b) Without metabolic activation: up to 5 µL/plate
- Vehicle: Corn oil
- Remarks - Method: Concentrations were chosen on the basis of a preliminary test with TA100, with no cytotoxicity seen at concentrations up to 50 µL/plate.
  No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µL/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 50	≥ 5	≥ 5	negative
Test 2		≥ 5	≥ 5	negative
Present				
Test 1	≥ 50	≥ 5	≥ 5	negative
Test 2		≥ 5	≥ 5	negative

- Remarks - Results: The test material was tested up to the maximum recommended dose level of 5 µL/plate. No toxicologically significant increases in the frequency of

revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.

All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Vivotecnia (2010)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	Not reported
Analytical Monitoring	The emitted Co_2 was analysed by using a TOC multi N/C 2100S, Analytik Jena.
Remarks - Method	The test was conducted according to the above mentioned OECD test guidelines. No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
2	8.1	2	27.8
4	14.6	4	68.5
14	53.1	14	84.0
29	62.9	29	72.1

Remarks - Results	All validity criteria for the test were satisfied. The reference control reached the pass level of 60% after 4 days. The toxicity control exceeded 25% biodegradation (required by guideline) showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance at the end of the 10-day window was 50%. The degree of degradation of the test substance 63% within the 28 days test period. Therefore, the test substance is not readily biodegradable according to the OECD (301 B) guideline.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	LAUS (2008)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static.
Species	Zebra fish (*Danio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	Not reported
Water Hardness	200 – 250 mg $CaCO_3$/L
Analytical Monitoring	Not reported
Remarks – Method	The test was conducted according to the guidelines above. No significant deviations from the test guidelines were reported. The test solution was prepared as a Water Accommodated Fraction (WAF). The WAF solution was prepared by adding test substance (1,001 mg) to the aqueous algae test medium (1 L). The solution was gently stirred by means of magnetic stirring to obtain a vortex of about 1/3 (or less in some conditions) of the height between the top and the bottom of the flask for 68 hours, followed by a phase separation period of four hours. The aqueous phase containing

the soluble substances, the WAF, was taken to perform the test. The test solution was clear during the assay observed by a spectrophotometer at 670 nm.

RESULTS

Nominal Concentration mg/L (WAF)	*Number of Fish*	*Mortality (%)*			
		24 h	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0
1,001	10	0	0	0	0

EL50 > 1,001mg/L (WAF) at 96 hours
NOEL 1,001 mg/L (WAF) at 96 hours
Remarks – Results All validity criteria for the test were satisfied. The 96-hour EL50 was calculated to be greater than 1,001 mg/L (WAF). The results are based on the nominal concentrations.

CONCLUSION The notified chemical is not harmful to fish

TEST FACILITY BfB (2011)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static
Species *Daphnia magna*
Exposure Period 48 hours
Auxiliary Solvent Not reported
Water Hardness 200 - 250 mg $CaCO_3$/L
Analytical Monitoring None reported
Remarks - Method The test was conducted according to the guidelines above. No significant deviations from the test guidelines were reported. The test solution was prepared as a Water Accommodated Fraction (WAF). The WAF solution was prepared by adding test substance (1,001 mg) to the aqueous algae test medium (1 L). The solution was gently stirred by means of magnetic stirring to obtain a vortex of about 1/3 (or less in some conditions) of the height between the top and the bottom of the flask for 68 hours, followed by a phase separation period of four hours. The aqueous phase containing the soluble substances, the WAF, was taken to perform the test. The test solution was clear during the assay observed by a spectrophotometer at 670 nm.

RESULTS

Nominal Concentration mg/L (WAF)	*Number of D. magna*	*Cumulative % Immobilised*	
		24 h	*48 h*
Control	20	0	0
1,001	20	0	0

EL50 > 1,001 mg/L (WAF) at 48 hours
NOEL 1,001mg/L (WAF) at 48 hours
Remarks - Results All validity criteria for the test were satisfied. The 48-hour EL50 was calculated to be greater than 1,001 mg/L (WAF). The results are based on the nominal concentrations.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates

TEST FACILITY BfB (2011)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	Freshwater green algae (*Pseudokirchneriella subcapitata*)
Exposure Period	72 hours
Concentration Range	0, and 1,011 mg/L
Auxiliary Solvent	None reported
Analytical Monitoring	None reported
Remarks - Method	The test was conducted according to the guidelines above. No significant deviations from the test guidelines were reported. The test solution was prepared as a Water Accommodated Fraction (WAF). The WAF solution was prepared by adding test substance (1,011 mg) to the aqueous algae test medium (1 L). The solution was gently stirred by means of magnetic stirring to obtain a vortex of about 1/3 (or less in some conditions) of the height between the top and the bottom of the flask for 68 hours, followed by a phase separation period of four hours. The aqueous phase containing the soluble substances, the WAF, was taken to perform the test. The test solution was clear during the assay observed by a spectrophotometer at 670 nm.

RESULTS

Biomass		*Growth*	
EL50	*NOEL50*	*EL50*	*NOEL*
mg/L (WAF) at 72 h	*mg/L (WAF) at 72 h*	*mg/L (WAF) at 72 h*	*mg/L (WAF) at 72 h*
-	-	> 1,011	1,011

Remarks - Results	All validity criteria for the test were satisfied. The 72-hour EL50 was calculated to be greater than 1,011 mg/L (WAF). The results are based on the nominal concentrations.
CONCLUSION	The notified chemical is not harmful to algae
TEST FACILITY	BfB (2011)

BIBLIOGRAPHY

BfB (2011) Ecotoxicological Tests. Belgium, Laboratoire d'Analyses de Fluides (Unpublished report submitted by the notifier).

BfB (2012) Solubility in Water According to OECD 105 (January, 2012). Belgium, Laboratoire d'Analyses de Fluides (Unpublished report submitted by the notifier).

LAUS (2008) Study Report Following OECD 301B: Biodegradability of [Notified Chemical] under Aerobic Conditions (October, 2008). Germany, LAUS GmbH (Unpublished report submitted by the notifier).

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia.

Phycher (2010) Evaluation of Acute Oral Toxicity in Rats – Up and Down Proceedure (Study No. TAO425-PH-10/0180, 31 August, 2010). Cestas, France, Phycher *Bio développement* (Unpublished report submitted by the notifier).

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

Trommer H. and Neubert R. H. H. (2006) Overcoming the Stratum Corneum: The Modulation of Skin Penetration. Skin Pharmacol Physiol, **19**:106-121.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.

US EPA (2012) Estimations Programs Interface Suite™ for Microsoft® Window, v 4.10. United States Environmental Protection Agency. Washington, DC, USA.

Vivotecnia (2010) Bacterial Reverse Mutation Test (Study No. B-01093, 20 October 2010). Madrid, Spain, Vivotecnia Research S.L. (Unpublished report submitted by the notifier).