File No: STD/1458

October 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Ethanol, 2-[(2-ethylhexyl)oxy]-

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

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

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

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/1458	Eastman Chemical Limited	Ethanol, 2-[(2-ethylhexyl)oxy]-	Yes	≤ 50 tonnes per annum	Component of coatings

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 for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Skin corrosion/irritation (category 2)	H315 – Causes skin irritation
Serious eye damage/eye irritation (category 2A)	H319 – Causes serious 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:
R36/38: Irritating to eyes and skin

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

Hazard classification	*Hazard statement*
Acute category 3	H402 – Harmful to aquatic life

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

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

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

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - H315 – Causes skin irritation
  - H319 – Causes serious eye irritation

- Classification of products/mixtures containing the notified chemical should be considered based on the concentration of the notified chemical present.

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 as introduced and during reformulation of coatings (at > 80% concentration):
  - Local exhaust ventilation during reformulation of coatings
  - Enclosed, automated processes when possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified chemical as introduced and during reformulation of coatings (at > 80% concentration) or in formulated products (at concentration ≤ 10%):
  - Avoid contact with skin and eyes
  - Maintain good hygiene practices

- 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 as introduced and during reformulation of coatings (at > 80% concentration):
  - Chemical resistant gloves
  - Safety glasses or face mask
  - Coveralls
  - Respiratory protection if ventilation is inadequate

- 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 in formulated products (at concentration ≤ 10%):
  - Gloves
  - Safety glasses
  - Coveralls

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System 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 to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain

circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

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

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

No additional secondary notification conditions are stipulated.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Eastman Chemical Limited (ABN: 40003039405)
C/- PricewaterhouseCoopers, Level 1 Darling Park, Tower 2, 201 Sussex St, Sydney NSW 3214

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: analytical data, degree of purity, residual monomers, impurities, additives/adjuvants, specific 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 except water solubility and partition co-efficient. Skin sensitisation and genotoxic human health endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CER/45, CEC/812

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Eastman™ EEH Solvent (> 80 % notified chemical)

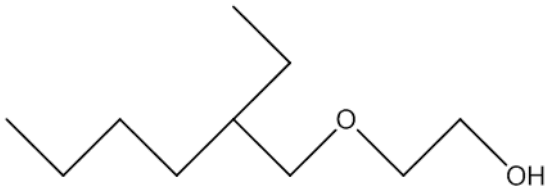
CAS NUMBER
1559-35-9

CHEMICAL NAME
Ethanol, 2-[(2-ethylhexyl)oxy]-

OTHER NAME(S)
Ethylene glycol mono-2-ethylhexyl ether
EGEhE

MOLECULAR FORMULA
$C_{10}H_{22}O_2$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
174.28

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 80 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear, colourless liquid

Property	Value	Data Source/Justification
Melting Point	-2.65 °C	Calculated (MPBVP v1.43; US EPA, 2011)
Boiling Point	235 °C at 101.3 kPa	SDS
Density	882 kg/m^3 at 21 °C	SDS
Vapour Pressure	0.003 kPa at 20 °C	Technical Data Sheet
Water Solubility	1.14 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains no hydrolysable functionality
Partition Coefficient (n-octanol/water)	log Pow = 2.86 at 20 °C	Measured
Adsorption/Desorption	log Koc = 2.0 at 25 °C	Calculated (KOCWIN v.2.00; US EPA, 2011)
Dissociation Constant	Not determined	Contains no readily dissociable functionality
Flash Point	102 °C at 101 kPa (closed cup)	SDS
Autoignition Temperature	> 227 °C	SDS
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties.

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

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

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not

recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia in neat form (> 80% purity) to be reformulated into finished coating products at up to 10% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-50	10-50	10-50	10-50	10-50

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Eastman Chemical Limited

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 205 L steel drums and transported from the port to formulators' warehouses by road. The finished products (coatings containing ≤ 10% notified chemical) will be packaged and transported to customers by road in 205L drums or 5-20 L steel cans.

USE
The notified chemical will be used as a component of water based coatings for professional and home use. Product types containing the notified chemical may include architectural, automotive, can and coil, floor polishes and general industrial coating products at up to 10% concentration. The products may be applied to a range of substrates by brush, roller or spray.

OPERATION DESCRIPTION
Reformulation
The notified chemical (> 80% concentration) will be formulated into various coating products (containing ≤ 10% notified chemical). Reformulation will be mostly an automated process. The notified chemical will be transferred from the drum by metered dosing into a closed mixing vessel. Samples will then be taken for quality control purposes. Filling containers with the final product (containing ≤ 10% notified chemical) will be an automated process conducted under exhaust ventilation.

End use - Professionals
The formulated coating products (containing ≤ 10% notified chemical) may be used undiluted or diluted further with a solvent prior to application. The coatings will then be applied to various substrates by brush, roller or spray.

End use - Public
Members of the public may use products containing the notified chemical at concentrations of up to 10% for architectural coatings and floor polishes (approximately 3% of the total import volume). These coatings will typically be applied with roller or brush, though a small portion may be applied using spray.

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 storage	1-2	20

Reformulation	4-8	20
QC staff	1	20
Maintenance	1-2	20
Professionals (e.g Painters)	8	300

EXPOSURE DETAILS

Transport and storage

Storage and transport workers are not expected to be exposed to the notified chemical, except in the unlikely event of an accidental container rupture.

Reformulation

Dermal, ocular and possibly inhalation exposure of workers to the notified chemical (at > 80% concentration) may occur during transfer processes, blending, cleaning and maintenance tasks. However, exposure is expected to be minimised by the use of mostly automated processes, local exhaust ventilation and appropriate personal protective equipment (PPE), including protective clothing, impervious gloves, goggles and respirators if ventilation is inadequate.

End use - Professionals

Under the proposed use scenario, professionals (e.g painters) may be exposed to coatings containing the notified chemical (at ≤ 10% concentration). Exposure is expected to occur predominantly via the dermal route, with ocular and inhalation exposure also possible, particularly when products are applied by spray. The potential for exposure should be minimised through the use of safe work practices and PPE by workers (goggles, impervious gloves, appropriate clothing and respiratory protection during spray application). When applied by spray, ventilated, automated and enclosed spray booths will usually be used. The majority of the coatings (90% import volume) containing the notified chemical are expected to be applied in this manner. If products containing the notified chemical are applied by spray outside a spray booth, respirators are expected to be worn to avoid inhalation of the aerosol. When applied by brush or roller, the products are expected to be used in well ventilated areas.

6.1.2. Public Exposure

Finished coatings containing the notified chemical at ≤ 10% concentration will be available for use by the general public and may comprise up to 3% of the total import volume.

Dermal and ocular exposure of the public to the notified chemical may occur during applications using brush and roller, particularly during the manual decanting and the manual applications, and cleaning of equipment. Inhalation exposure is also possible when products are applied by spray. Exposure is expected to be lowered by use in well ventilated areas where possible and if members of the public wear PPE during coating application, exposure will be further minimised.

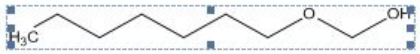
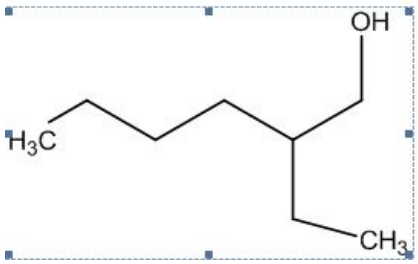
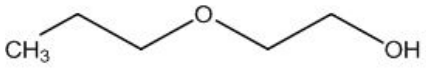
The general public may come in contact with articles or surfaces coated with products containing the notified chemical; however the notified chemical will be cured into the inert matrix and will not be bioavailable.

6.2. Human Health Effects Assessment

Only limited data was available on the notified chemical.

Some glycol ethers are considered of concern for a range of adverse health effects, including repeated dose effects, irritation, hemolysis, bone marrow damage, liver and kidney damage, central nervous system (CNS) depression, and developmental and reproductive toxicity (US EPA, 2010).

Therefore, additional information on a number of glycol ethers or related analogues has been used to ascertain the likely health effects of the notified chemical. Two analogue chemicals(*) were provided by the notifier and a further analogue chemical(**) was identified by QSAR. Analogue 1 was considered to be an appropriate analogue due to the similarity of the chain lengths, whilst analogue 2 was considered useful in order to characterise the potential influence of the ethyl hexyl functional group on the likely toxicity of the notified chemical. The analogue identities are summarised below:

CAS number	Chemical name	Structure	MW	Classification on HSIS
Analogue 1 112-25-4* (OECD SIDS 2004)	Ethanol, 2-(hexyloxy)-		146	Xn R21/22 C; R34
Analogue 2 104-76-7** (SIAM 1995)	1-Hexanol, 2-ethyl-		130	Xn; R21 Xi; R36,37,38
Analogue 3 2807-30-9* (OECD SIDS 2004)	Ethanol, 2-propoxy-		104	Xn; R21 Xi; R36

The table below summarises much of the available hazard data on the notified chemical and analogues. Further relevant hazard information is discussed below the table.

Endpoint	Test Substance	*Result and Assessment Conclusion*
Rat and mouse, acute oral toxicity	Notified chemical	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, acute dermal toxicity	Notified chemical	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	Analogue 1	LC50 > 85 ppm (> 508 mg/m^3, 4 hr); low toxicity
Rabbit, skin irritation	Notified chemical	irritating
Rabbit and guinea pig, eye irritation	Notified chemical	irritating
Guinea pig, skin sensitisation	Notified chemical	no evidence of sensitisation
Rat, repeat dose oral toxicity – 31 doses.	Notified chemical	LOAEL = 590 mg/kg bw/day
Rat, repeat dose oral toxicity – 29 - 33 doses.	Notified chemical	LOAEL = 957 mg/kg bw/day
Rat, repeat dose oral toxicity – 90 days.	Analogue 2	NOAEL = 125 mg/kg/day
Rat, repeat dose inhalation toxicity – 90 days.	Analogue 2	NOAEL ≥ 0.639 mg/L/day
Genotoxicity – Ames tests and in vitro cytogenicity and sister chromatid exchange assays in Chinese Hamster Ovary Cells	Analogue 1	non genotoxic
Genotoxicity – Salmonella mutagenicity tests and chromosomal aberration tests (*in vitro* and in *vivo*).	Analogue 2	non genotoxic
Rat and rabbit, reproductive and developmental toxicity by inhalation	Analogue 1	NOAEL > 474 mg/m^3
Rat and rabbit, reproductive and developmental toxicity by oral route	Analogue 2	NOAEL = 130 mg/kg

Toxicokinetics, metabolism and distribution
The notified chemical is expected to be readily absorbed via the skin, GI tract and inhalation routes based on its low molecular weight (< 500 Da) and relative hydrophilicity.

Monosubstituted glycol ethers, such as Analogue 1, are expected to be metabolised to alkoxyacetic acids, which are the major urinary metabolites (OECD, 2004). There appears to be no evidence of metabolism of the ether linkage. A similar metabolism pathway is expected for the notified chemical, resulting mainly in conversion to acetic acid, 2-[(2-ethylhexyl)oxy]-. Metabolism of the ether linkage to form analogue 2 or a closely related chemical is not expected to occur.

Analogue 2 was reported to be rapidly and extensively absorbed via the gastrointestinal tract in rats and rabbits but percutaneous absorption through rat skin was low (SIAM 1995). Observed toxicity via oral and inhalation routes indicated that analogue 2/metabolites were distributed to several target organs, including liver, kidney and stomach. The excretion of analogue 2/metabolites following oral administration was rapid and extensive occurring mainly via the urine in rats and rabbits.

Acute toxicity
The notified chemical was found to be of low acute oral toxicity in two separate studies, with LD50 values of > 2000 mg/kg bw (refer to Appendix B.1 and B.2 for study details). Some animals that died during the study showed bloody urine and/or blood in the stomach and/or intestines. In addition, the notified chemical was of low acute dermal toxicity.

Analogue 1 was reported to be of low toxicity via inhalation with no lethality or toxic effects observed in studies in rodents (OECD, 2004).

Based on the available information, the notified chemical is expected to be of low acute toxicity (oral, dermal and inhalation).

Irritation
Brief study summaries report that the notified chemical produced moderate irritation of rabbit and guinea pig skin. This is also consistent with the moderate irritation effects noted in the acute dermal toxicity study on the notified chemical (refer to Appendix B.2).

In addition, a brief study summary provided by the notifier on the notified chemical reported that it produced moderate eye irritation in rabbits. This included moderate erythema, slight to moderate edema of the conjunctiva and nictitating membranes, slight opacities of the cornea and fluorescein staining of the cornea and adnexae.

The notified chemical was classified as irritating to the skin and eyes in the SDS provided.

Analogue 1 is classified as hazardous with the risk phase ‘corrosive’ (Xi; R34) on the HSIS (Safe Work Australia).

Analogue 2 was moderately irritating to rabbit skin and a moderate-to-severe irritant to the eye in rabbits (SIAM 1995).

Based on the data available the notified chemical is irritating to the skin and eyes.

Sensitisation
In general, monoalkyl glycol ethers do not appear to be sensitisers (NICNAS). A brief study summary provided by the notifier, reports that the notified chemical did not result in positive skin sensitisation reactions in five tested guinea pigs.

Based on the data available the notified chemical is not expected to be a skin sensitiser.

Repeated dose toxicity
Effects reported in a repeat dose oral gavage study on the notified chemical (consisting of 31 doses over a period of 43 days) included:

- enlarged livers and increased absolute and relative liver weights in all treated groups;
- erosion of the stomach mucosa in several high dose animals;

- hyperkeratosis and acanthosis of the stomach in all high dose animals;
- hyaline degeneration of the proximate convoluted tubules of the kidneys in many of the treated animals in all dose groups, with severity increasing with increasing dose;
- slight increases in the relative kidney weights of high dose animals.

The lowest observed adverse effect level (LOAEL) in this study was established as 590 mg/kg bw/day (the lowest tested dose). Study details are provided in Appendix B.4.

Effects reported in a second oral repeat dose study on the notified chemical (consisting of 29-33 doses over a period of 44 days) included:

- decreases in haemoglobin concentrations in treated animals;
- increases in absolute and relative liver weights, together with enlarged livers;
- hepatocytomegally, aniosokaryosis, and lack of cytoplasmic basophilia in the livers of several treated animals;
- hyperkeratosis and acanthosis of the stomachs of many treated animals.

The lowest observed adverse effect level (LOAEL) in this study was established as 957 mg/kg bw/day (the lowest tested dose). Study details are provided in Appendix B.5.

For analogue 2, repeat dose 90-day toxicity studies have been performed (via the oral route (rat, mouse) and the inhalation route (rat)). Effects on the liver, stomach, and kidney degeneration were reported. For oral exposure the NOAEL was 125 mg/kg/day (rat), whilst the inhalation NOAEL was ≥ 0.639 mg/L/day. The NOAEL was < 1.66 g/kg/day for the available dermal route subacute studies (SIAM 1995).

Based on the available information, repeated oral or inhalation doses of the notified chemical may cause haemolytic effects in laboratory animals (see further discussion on haemolysis below) and effects on the liver, stomach and kidneys. It is noted that signs of acute toxicity consistent with haemolysis have been observed with other monoethylene glycol ethers; however, humans appear to be the least sensitive species for haemolytic effects (OECD SIDS 2004). As such, whilst the notified chemical may cause haemolytic effects in laboratory animals, this is unlikely to be of relevance to humans.

Mutagenicity/genotoxicity
Mutagenicity studies conducted on analogue 1 were negative (OECD SIDS 2004), including Ames tests and *in vitro* cytogenicity and sister chromatid exchange assays in Chinese Hamster Ovary Cells.

Analogue 2 was negative in Salmonella mutagenicity tests and chromosomal aberration tests (*in vitro* and *in vivo*). Other studies indicated that analogue 2 did not have genotoxic activity and carcinogenic potential was not demonstrated in studies in rats and mice (NOAEL rat = 50 mg/kg bw/day) (SIAM 1995).

Based on the available data the notified chemical is unlikely to be genotoxic.

Toxicity for reproduction/developmental toxicity
Although certain short chain monoethylene glycol ethers such as 2-ethoxyethanol (110-80-5) are known reproductive toxicants, the ability of the glycol ethers to cause testicular toxicity decreases with increasing chain length (OECD, 2004). As 2-butoxyethanol (111-76-2), which has a shorter chain than analogue 1, has been shown not to be a reproductive toxicant (OECD, 2004) analogue 1 is also considered not to be toxic to the reproductive system.

This is supported by studies on analogue 1, which indicated that analogue 1 was not selectively toxic to the reproductive system or developing fetus and developmental toxicity was secondary to maternal toxicity. The repeated dose toxicity studies in which reproductive organs were examined indicated that analogue 1 was not associated with toxicity to reproductive organs, including the testes (OECD SIDS 2004).

No developmental effects were noted (even at concentrations that produced maternal toxicity) in rabbits and rats exposed to analogue 1 by inhalation (OECD, 2004). The NOAEL for developmental toxicity via the inhalation route was determined to be > 474 mg/m^3 (rat and rabbit, analogue 1) (OECD SIDS 2004).

A US EPA report on analogue 2 concludes that it is not developmentally toxic.

Based on the available data the notified chemical is unlikely to cause reproductive or developmental toxicity.

Health hazard classification
Based on the available information, the notified chemical is 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. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Skin irritant (category 2)	H315 – Causes skin irritation
Eye irritant (category 2A)	H319 – Causes serious 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 phrase(s):
R36/38: Irritating to eyes and skin

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the limited data available, the notified chemical irritating to the skin and eyes.

Dermal, ocular and inhalation exposure of workers to the notified chemical at the imported concentrations of > 80% may occur during reformulation of coatings. At these concentrations, workers could be at risk of skin and eye irritation. The use of engineering controls (particularly the automation of processes and local exhaust ventilation) and personal protective equipment (skin and eye protection) during the reformulation of coatings is expected to minimise exposure and reduce the risk of such effects.

Dermal, ocular and inhalation exposure of workers to the notified chemical at concentrations ≤ 10% may occur during coating application (spray, brush or roller). At these concentrations, the risk of adverse health effects from the notified chemical is expected to be minimised by the engineering controls, such as spray booths, and personal protective equipment, such as respiratory protection, gloves and overalls.

In conclusion, the occupational health and safety risk associated with the notified chemical is not considered to be unacceptable when engineering controls (including automated processes, spray booths and local exhaust ventilation) and PPE (skin and eye protection) are used during reformulation and application of coatings.

6.3.2. Public Health
DIY users may be exposed to the notified chemical at concentrations ≤ 10% via the dermal, ocular or inhalation routes. However, given the infrequent exposure and low concentration of the notified chemical in coating products, irritation effects are not expected to occur.

The general public may also be exposed to substrates coated with the notified chemical (≤ 10%). However, the notified chemical will be dried and cured and is not expected to be significantly bioavailable.

In conclusion, the risk to public health associated with exposure to the notified chemical is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported into Australia as a raw material for reformulation into coating/paint products. Accidental spills or leaks of the notified chemical during reformulation are expected to be collected for appropriate disposal, most likely to landfill. A minimal amount of the notified chemical may be lost during reformulation as a result of equipment cleaning. Waste water containing residues of the notified chemical is expected to be recycled into subsequent batches of paints/coatings.

RELEASE OF CHEMICAL FROM USE

During the end-use of the coating/paint products into which the notified chemical is incorporated, a portion of the notified chemical may evaporate to the atmosphere when the coating/paint is curing. Up to 10-20% of the introduced volume of notified chemical will also be lost as overspray, as the majority of the coating containing the notified chemical (90% of the import volume) will be applied in a spray booth in industrial settings. The overspray is expected to be collected with engineering controls, and disposed of according to local, state and federal regulations.

When used in a non-industrial setting, some release of the notified chemical to the sewage system is expected as a result of equipment cleaning.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues in empty shipping containers containing the neat notified chemical are expected to be disposed to landfill with the containers or left to evaporate. If shipping containers are cleaned for reuse with an appropriate solvent, it is expected that residues will be collected for appropriate disposal. Coated articles at the end of their useful life and solid waste containing residues of the notified chemical are expected to be disposed of to landfill.

7.1.2. Environmental Fate

Details of environmental fate data can be found in Appendix C. The notified chemical is volatile, and has the potential to evaporate to the atmosphere, given its intended use pattern. The predicted rate constant with hydroxyl radicals is expected to be high, with a predicted half-life in air of 4 hours (AOPWIN v.1.92; US EPA 2011). The notified chemical is therefore not expected to persist in the air compartment.

Notified chemical released to sewer from the washing of equipment is likely to remain in the water column due to its solubility. The notified chemical is ready biodegradable; if released to surface waters in treated effluent, the notified chemical is expected to disperse and degrade. It is not expected to bioaccumulate, based on its low n-octanol/water partition coefficient and water solubility.

If disposed of to landfill as residues in empty import container or solid wastes, the notified chemical is expected to either partition to atmosphere, or degrade biotically or abiotically to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation of the Predicted No-Effect Concentration (PNEC) for aquatic compartments is summarised in the table below. Based on the reported use in paints/coating for professionals and DIY users, it is conservatively assumed that 5% of the total import volume of the notified chemical is released to sewer on a nationwide basis over 365 days per year.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	2,500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	6.85	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:	1.51	µg/L
PEC - Ocean	0.15	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 1.5 µg/L may potentially result in a soil concentration of approximately 10.1 µg kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 50.5 µg/kg and 101 µg/kg,

respectively. However, these are likely to be maximum values given the potential for the notified chemical to evaporate into the atmospheric compartment.

7.2. Environmental Effects Assessment

Endpoints provided by the notifier indicate that the notified chemical has median lethal concentrations (LC50s) in the range 10-100 mg/L for minnows, daphnids, scuds, flatworms and sow bugs. However, only a very brief summary of these endpoints was provided and details of the testing methods or raw data were not provided (Health, Safety and Human Factors Laboratory, 1982). These endpoints are summarised below.

Calculated QSAR data (Neutral Organics, ECOSAR v1.1; US EPA, 2011) further supports the empirical endpoints provided for the notified chemical, and the predicted endpoints are also summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Notified Chemical – Empirical data		
Fish	LC50 = 10 - 100 mg/L	Harmful to fish
Daphnia	LC50 = 10 - 100 mg/L	Harmful to aquatic invertebrates
Notified Chemical - ECOSAR		
Fish Toxicity (96 h)	LC50 = 56 mg/L	Harmful to fish
Daphnia Toxicity (48 h)	EC50 = 33 mg/L	Harmful to aquatic invertebrates
Algal Toxicity (72 h)	EC50 = 29 mg/L	Harmful to algae

On the basis of the empirical and predicted endpoints, the notified chemical is considered to be harmful to fish, aquatic invertebrates and algae. On this basis, the notified chemical is formally classified under the Globally Harmonised System of Classification of Chemicals (GHS; United Nations, 2009) as Acute Category 3: Harmful to Aquatic Life. On the basis of its ready biodegradability and low n-octanol/water partition coefficient (log Pow = 2.86), the notified chemical is not classified for long term hazard.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated using the lower limit of the empirically determined LC50 value of 10 mg/L. The ECOSAR predictions are expected to be reliable for this class of chemical and the predictions also support the available empirically determined endpoints. On the expected reliability of the endpoints, and as endpoints for three trophic levels are available, an assessment factor of 100 was used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Fish).	10	mg/L
Assessment Factor	100	
PNEC:	100	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	1.51	100	0.015
Q - Ocean:	0.15	100	0.002

As the risk quotients are less than 1 considering a conservative release scenario, the notified chemical is not expected to pose an unreasonable risk to the environment when it is introduced at the proposed maximum annual importation volume and used as proposed.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 1.14 g/L at 20 °C

Method	OECD TG 105 Water Solubility. EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks	Flask Method. On completion of the equilibration period, samples had excess test solution present on the water's surface. After centrifugation, the supernatant was taken for GC analysis. The final pH of the solutions was 5.8.
Test Facility	Harlan (2012)

Partition Coefficient (n-octanol/water) log Pow = 2.86 at 20 °C

Method	OECD TG 107 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	Shake Flask Method.
Test Facility	Harlan (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical (> 99.5% purity)

METHOD: Similar to OECD TG 401 Acute Oral Toxicity.
- Species/Strain: Rat/Charles River COBS, CD, BR; Mice/Charles River COBS, CD-1
- Vehicle: None
- Remarks - Method: Five dose groups of five rats and five mice (separate groups of both fasted and fed animals) were administered the notified chemical by oral gavage. Exact dose levels were not recorded in the study report, though they were indicated to range from 2.6 mM to 168 mM/kg bw and to be incremented by a factor of 2. Following administration, animals were observed twice daily on weekdays throughout a two week period.

RESULTS

	LD50 in rats (mg/kg bw)	*LD50 in mice (mg/kg bw)*
Fasted	7832	7308
Fed	5149	3898

- Signs of Toxicity: Inactivity, laboured breathing, rapid respiration, anorexia, slight to moderate weakness, prostration and death were observed in both fasted and fed animals. The majority of deaths occurred in the first three days. Hematuria was observed in the intermediate dose levels of the fed rats.
- Effects in Organs: Effects in animals that died during the observation period may have included bloody urine and/or blood in the stomach and/or intestines (note some uncertainty due to the brief details reported). Such effects were not observed in animals that survived the observation period.

CONCLUSION: The notified chemical is of low toxicity via the oral route.

TEST FACILITY: Unspecified test laboratory (1981a)

B.2. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical (> 80% concentration)

METHOD: Similar to OECD TG 401 Acute Oral Toxicity.
- Species/Strain: Mice/Charles River COBS, CD-1
- Vehicle: None
- Remarks - Method: Five dose groups of five mice (separate groups of both fasted and fed animals) were administered the test substance by oral gavage. Following administration, animals were observed twice daily on weekdays throughout a two week period.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1A	5 fasted males	944	Not reported
1B	5 fed males	944	Not reported
2A	5 fasted males	1906	Not reported
2B	5 fed males	1906	Not reported
3A	5 fasted males	3812	Not reported
3B	5 fed males	3812	Not reported
4A	5 fasted males	7623	Not reported

4B	5 fed males	7623	Not reported
5A	5 fasted males	15246	Not reported
5B	5 fed males	15246	Not reported

LD50	Fasted mice: 3070 mg/kg bw Fed mice: 5778 mg/kg bw
Signs of Toxicity	Slight to severe weakness, laboured breathing, prostration and death. Deaths occurred within hours to two days after dosing.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Unspecified test laboratory (1981xxxx)

B.3. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical (> 99.5% purity)
METHOD	Similar to OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rabbit/New Zealand White
Vehicle	None
Type of dressing	Occlusive.
Remarks - Method	The notified chemical was administered to the clipped, unabraded back of the animals and held with an occlusive wrap. The wrap was removed after 24 hours and dermal responses were scored on days 1, 3, 7, 10 and 14.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	1827	Not reported
2	5 males	3654	Not reported
3	5 males	7308	Not reported
4	5 males	14616	Not reported

LD50	2584 mg/kg bw
Signs of Toxicity - Local	Irritation described as moderate was observed.
Signs of Toxicity - Systemic	Observations at lower doses included anorexia, slight depression, cyanosis, ataxia, and soft faeces. Observations at higher doses included salivation, nasal discharge, iritis, significant depression, laboured breathing and prostration.
Effects in Organs	Some effects were observed in the kidneys of the rabbits, and there was reddish coloured fluid in the urinary bladder of a small number of animals, though these effects were mainly in the lower dose groups (groups 1 and 2).
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Unspecified test laboratory (1981xxx)

B.4. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical (> 80% concentration)
METHOD	Not specified
Species	Rats
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 43 days Total number of doses: 31
Vehicle	None

Remarks - Method Minimal details provided

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	10 males	0	Not reported
low dose	10 males	590	Not reported
mid dose	10 males	1180	Not reported
high dose	10 males	2360	Not reported

Mortality and Time to Death

One high dose rat lost weight and became weak and depressed during the fifth week of the study and was euthanized and autopsied on day 38. This animal had no body fat, reduced muscle mass, an enlarged and dark coloured liver, dark coloured blood and bone marrow, erosion of the mucosa of the stomach, distended intestines and urinary bladder, hyperkeratosis and acanthosis of the stomach, congested bone marrow, focal inflammation and multiple cysts in the kidneys, dilation of the renal pelvis, hyaline degeneration of the proximate convoluted tubules, and crystals present in the renal tubules.

Clinical Observations

A dose-dependent reduction in body weight gain was observed by the end of treatment, though it was only statistically significant in the high dose group. The mid and high dose animals consumed slightly less food than the control and low dose groups.

Depression and a brownish deposit around the prepuce and the hair of the abdomen were noted in mid and high dose animals. Some of the high dose animals were prostrate and appeared to have dried blood around the nose. One high dose rat had bloody urine after three weeks of treatment.

Relative kidney, testes, brain and adrenal gland weights were slightly increased in high dose animals. The absolute heart weights of mid and high dose animals was slightly decreased. Absolute and relative liver weights were increased in all treated groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Statistical differences from controls were noted in the high dose group, with the serum levels of glutamic oxaloacetic transaminase decreased, the serum levels of alkaline phosphatase increased and the serum levels of glucose decreased.

Effects in Organs

Enlarged livers were observed in all treated groups:
High dose: 8/9 animals
Mid dose: 4/10 animals
Low dose: 1/10 animals

The stomach mucosa was eroded in 3/9 high dose animals and one had a stomach ulcer. Minor to moderate hyperkeratosis and acanthosis of the stomach was observed in all high dose animals. Hyaline degeneration of the proximate convoluted tubules of the kidneys was observed in the majority of animals in all dose groups, with the severity of the effect decreasing with decreasing dose.

CONCLUSION

The Lowest Observed (Adverse) Effect Level (LO(A)EL) was established as 590 mg/kg bw/day in this study, based on the effects in the liver and kidneys.

TEST FACILITY Unspecified test laboratory (1981xxx)

B.5. Repeat dose toxicity

TEST SUBSTANCE Notified chemical (> 99.5% purity)

METHOD Similar to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in

	Rodents.
Species/Strain	Rat/Charles River, COBS, CD, BR
Route of Administration	Oral – gavage
Exposure Information	Total exposures: 29-33 doses over a period of 44 days Dose regimen: 5 days per week
Vehicle	None
Remarks - Method	Animals were observed daily on weekdays. Sensory reactivity and functional observations were not conducted. The study did not examine the full range of haematological and clinical chemistry parameters recommended by the OECD test guideline.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	10 males	0	0/10
low dose	10 males	957	0/10
mid dose	10 males	1914	0/10
high dose	10 males	3828	10/10

Mortality and Time to Death

All high dose animals died during the study, with 9/10 rats dying after two to four treatments and the remaining animal dying on day 33. The remaining animal had bloody urine after 20 days, and unkempt coat, it was moderately weak and had a distended urinary bladder.

Clinical Observations

Significant reductions in body weight gain and feed consumption was observed in the high dose group. Mean terminal body weights were significantly reduced in all dose groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

The mid and low dose groups showed statistically significant decreases in haemoglobin concentration.

Absolute and relative liver weights showed statistically significant increases in mid and low dose groups. The relative kidney, heart and testes weights showed statistically significant increases in mid and low dose groups. Mid dose group animals appeared to have urinary incontinence.

Effects in Organs

Three animals from the high dose group had blood in the urinary bladder, three animals from the mid dose group had enlarged livers and one of these also had enlarged kidneys.

Incidences of the observed liver effects are summarised below:

	Control	*Low*	*Mid*	*High*
Hepatocytomegally	0/10	1/10	5/10	0/10
Aniosokaryosis	0/10	10/10	7/10	3/10
Lack of cytoplasmic basophilia	0/10	0/10	7/10	2/10

Some high dose animals showed degenerated spermatozoa of the epididymides (2/10 animals) and diffuse haemorrhage of the thymus (5/10 animals) with no effects noted in other dose groups.

All mid and low dose animals displayed hyperkeratosis and acanthosis of the stomach, with a smaller number of high dose animals showing these effects (3/10 and 2/10 animals, respectively).

Four of ten high dose animals displayed bone marrow vacuolation.

Congestion of the spleen was observed in 3/10 high dose animals and 9/10 mid dose animals.

Note: The lower incidence of some of the above effects in high dose animals may have been due to the

premature deaths of all animals at this dose group, thus not allowing sufficient time for development of the effects.

Remarks – Results
Minimal details provided in study report.

CONCLUSION
The Lowest Observed (Adverse) Effect Level (LO(A)EL) was established as 957 mg/kg bw/day in this study.

TEST FACILITY Unspecified test laboratory (1982xxx)

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	None reported
Analytical Monitoring	Shimadzu TOC-V-CPH Carbon Analyser
Remarks - Method	Conducted in accordance with the guidelines above and GLP compliance. As the test substance was reported to be insoluble, the test substance (~45 mg) was weighed onto silica gel (~100 mg) and placed in each respective test or control vessel.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
1	1.6	1	7.3
9	10.5	9	81.6
17	66.5	17	82.8
28	90.4	28	80.9

Remarks - Results	All validity criteria were met. The toxicity control achieved 57% biodegradation by day 13, indicating that the test substance was not toxic to microorganism respiration. As the test substance reached > 60% degradation within the 10-day window, it is considered readily biodegradable.
CONCLUSION	The notified chemical is readily biodegradable.
TEST FACILITY	Smithers Viscient (2011)

BIBLIOGRAPHY

ACGIH (American Conference of Governmental Industrial Hygienists). Documentation of the Threshold Limit Values for Chemical Substances, ACGIH Signature Publications, 7th Edition, 2011.

ConsExpo (2006) Consumer Exposure and Uptake Model, ConsExpo, version 4.1. National Institute for Public Health and the Environment, The Netherlands.

Health, Safety and Human Factors Laboratory (1982) Environmental Test Report (Study number: BC-82-EN22, October 1982). Rockchester, NY, Health, Safety and Human Factors Laboratory, Eastman Kodak Company. (Unpublished report submitted by the notifier).

Harlan (2012) Ethanol, 2-(ethylhexyl) oxy-: Determination of Physico-Chemical Properties (Study No. 41202069, November 2012). Shardlow, Derbyshire, UK, Harlan Laboratories Ltd., Eastman Chemical Company. (Unpublished report submitted by the notifier).

National Industrial Chemical Notification and Assessment Scheme (NICNAS). Human health assessment for Ethanol, 2-(hexyloxy)- (CAS No. 112-25-4). Australian Government Department of Health and Ageing. Accessed July 2013 at http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=83

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

OECD (2004) SIAR category assessment for monoethylene glycol ethers. Accessed July 2013 at http://webnet.oecd.org/hpv/UI/handler.axd?id=c0edaa0e-2885-4ebe-a102-135ed2bc2da3

OECD (2009) SIAP& SIDS on 2-(1-methyletoxy)ethanol (109-59-1). Accessed July 2013 at http://webnet.oecd.org/HPV/UI/SIDS_Details.aspx?Key=bc5c93e3-f52b-41e4-8183-cb991adf1cc1&idx=0

RIVM (2009) The ConsExpo spray model Modelling and experimental validation of the inhalation exposure of consumers to aerosols from spray cans and trigger sprays. RIVM Report 320104005/2009. RIVM, P.O. Box 1, 3720 BA Bilthoven, the Netherlands.

RIVM (2010) New default values for the spray model. RIVM, March 2010.

SIAM (1995) 2-Ethylhexanol (CAS No. 104-76-7): SIDS Initial Assessment Profile SIAM 3, 13-15 February 1995.

Smithers Viscient (2011) Eastman EEH Solvent – Determination of the Biodegradability of a Test Substance Based on OECD Method 301B (CO2 Evolution Test) (Study No. 13893.6141, March, 2011). Smithers Viscient, Wareham, Massachusetts, Eastman Chemical Company (Unpublished report submitted by the notifier).

SWA (2012) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/spray-painting-and-powder-coating.

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.

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 (2010) TSCA New Chemicals Program Chemical Categories. United States Environmental Protection Agency. Washington DC, USA, http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf.