File No:LTD/1448

March 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polyalkyleneglycol ethylmethylether

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 the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, 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

FULL PUBLIC REPORT

Polyalkyleneglycol ethylmethylether

Full report amended on 23/06/2010.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Roland DG Australia Pty Ltd (ABN: 13007023690)

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical names, Other names, CAS Number, Molecular formula, Structural Formula, Molecular weight, Spectral data. Purity, Non-hazardous impurities, Details of use, Concentration in product and Import volumes.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting point, Boiling point, Vapour pressure, Water solubility, Hydrolysis as a function of pH, Partition coefficient, Absorption/Desorption, Dissociation constant, Flash point, Flammability limits, Autoignition Temperature, Reactivity and Bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polyalkyleneglycol ethylmethylether

3. COMPOSITION

DEGREE OF PURITY >98 %

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Unknown

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
Unknown

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Clear liquid with slightly specific odor

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-72°C	MSDS
Boiling Point	167.9°C at 101.3 kPa	Calculated
Density	908 kg/m^3 at 20°C	Calculated
Vapour Pressure	230 – 1100 Pa at 20°C	Analogue data
	318 Pa	Notified chemical
Water Solubility	Miscible with water	Analogue data
	76 g/L at 25°C	Notified chemical (calculated)
Partition Coefficient (n-octanol/water)	log Pow = -0.36	Analogue data
Adsorption/Desorption	log Koc = 0.66 - 1	Calculated
Flash Point	53.8°C at 101.3 kPa	Calculated
Flammability Limits	Upper: 33%	MSDS
	Lower: 2.5%	
Autoignition Temperature	169°C	MSDS

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

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

Dangerous Goods classification
Based on the modeled (calculated) flash point data in the above table the notified chemical is classified as follows according to the Australian Dangerous Goods Code (NTC, 2007):
Class 3 – Flammable liquid, Packing Group III.
However the data above does not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical/polymer.

5. INTRODUCTION AND USE INFORMATION

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

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

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

PORT OF ENTRY
Sydney and Melbourne

TRANSPORTATION AND PACKAGING
The ink containing the notified chemical will be imported in 1L inkjet cartridges (rigid plastic) containing 1 L hermetically sealed aluminum foil pack. The inkjet cartridges will be transported in cardboard boxes containing 6 cartridges each, by road or rail to the notifier's storage warehouse before being distributed to end user sites.

USE
The notified chemical is a component of commercial and industrial printing ink.

OPERATION DESCRIPTION

~~During printing, the imported ink containing the notified chemical at <30% will be transferred directly from the cartridge to the printing head via automated lines. The printing machine will be fully automated and is equipped with UV lamps that cure the product immediately after coating.~~

During printing, the imported ink containing the notified chemical at <30% will be transferred directly from the cartridge to the printing head via automated lines. The printing machine will be fully automated and is equipped with heaters that dry the product immediately after coating.

A local fume extraction is provided for the printing machine. The machine operator will insert and remove ink cartridges and will also handle the printed substrate once the ink has been fully cured.

Some of the notified chemical will be trapped in the matrix of the ink ingredients. Residual ink within printing equipment will be wiped clean using rags and solvents. These rags and dirty solvents will be disposed of by the printing company through licensed waste disposal contractors.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Storage & transport personnel	10-20	4	50
Printer operators	20	6	200
Service technicians	10	1	50

EXPOSURE DETAILS

Storage and transport personnel and workers are not expected to be exposed to the imported notified chemical, as they will be handling closed containers. Exposure to the notified chemical is possible only in the event of an accident where the packaging is breached.

During normal use, printer operators are not expected to have high exposure to the notified chemical at <30% in printing ink, as the process is mainly automated and the ink is contained in the inkjet cartridge.

Dermal exposure is possible during the replacement of ink cartridges (manual process) and during cleaning. However, operators will wear protective clothing, and impermeable gloves.

Inhalation exposure may occur but would be limited by the use of local exhaust ventilation employed in areas surrounding printing machines. After ink application to the substrate, the notified chemical will be trapped in the matrix of the ink and hence the notified chemical will be no longer bioavailable. However it may volatilise slowly from the matrix.

Service technicians will come in contact with the notified chemical during printer maintenance, where dermal or inhalation contact with residual ink is possible. Printer maintenance personnel will wear disposable cotton gloves and safety glasses.

6.1.2. Public exposure

The ink product containing the notified chemical will only be used for commercial purposes.

The public will not be exposed to the ink products containing the notified chemical at <30 % except in the event of accidental spillage during road transportation.

~~The general public may also come into contact with the cured substrate containing the notified chemical.~~ The general public may also come into contact with the cured substrate, containing the notified chemical trapped in the matrix. As the notified chemical will be substantially trapped in the matrix of the ink, it will not be significantly available

Therefore, public exposure to the notified chemical is expected to be negligible.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix B."

Endpoint	*Result and Assessment Conclusion*
Rabbit, skin irritation	irritating
Mutagenicity – bacterial reverse mutation	non mutagenic

Only limited toxicological data are available for the notified chemical. However information is available on the class of glycol ethers, and on a close analogue of the notified chemical.

In general, the acute effects of glycol ethers are limited to the central nervous system and are similar to acute solvent toxicity. These effects include dizziness, headache, confusion, fatigue, disorientation, slurred speech and (if severe enough) respiratory depression and loss of consciousness. The effects of long-term exposure include skin irritation, anaemia and bone marrow supression, encephalopathy and reproductive toxicity. (ILO, 2007)

Some glycol ethers are considered of concern for a range of adverse health effects, including repeated dose effects and developmental and reproductive toxicity. (USEPA, 2002)

Toxicokinetics, metabolism and distribution

The notified chemical has a molecular weight <500 and has considerable hydrophilicity. Based on the characteristics of the analogue, it would be readily absorbed through all routes, distributed throughout the body, metabolised, and the metabolites excreted through the urine.

Acute toxicity

No acute toxicity studies were provided for the notified chemical. Published data indicates that the oral LD50 (rat) is 6500 mg/kg bw and the acute dermal LD50 (rabbit) is 7070 mg/kg bw. (AIHA, 1962) Based on the data available, the notified chemical is expected to have low acute toxicity via oral and dermal routes. Acute inhalation toxicity data are not available for the notified chemical or the analogue.

Irritation and Sensitisation

In a study on rabbits, the notified chemical was irritating to the skin. No data were supplied on respiratory or eye irritation or on sensitisation potential. The analogue chemical was found to be slightly irritating to rabbit eyes (details of study not available).

Repeated dose toxicity

No repeat dose toxicity studies were provided for the notified chemical. Short term studies on the analogue chemical (< 28 days) showed effects on the male reproductive system (see below) and the hematopoietic system.

Mutagenicity

The notified chemical was not mutagenic to bacteria in vitro, with and without metabolic activation. Studies on the analogue chemical suggest that it is not genotoxic.

Toxicity for reproduction
No studies were available on the notified chemical. Studies on the analogue chemical indicate that it is a developmental and reproductive toxicant. The analogue is classified under the NOHSC Approved Criteria (2004) with the risk phrases:

R60 – May impair fertility
R61 – May cause harm to the unborn child

Health hazard classification
Based on the limited toxicology data provided, the notified chemical cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Data on the notified chemical and a close analogue indicate that it is likely to be irritating to skin and have irritation potential to eyes. Significant adverse reproductive and developmental effects seen after repeated exposure to a close analogue are expected to also be relevant to the notified chemical.

The ink containing the notified polymer at < 30% will be imported in cartridges and no formulation or packaging will take place in Australia. Dermal, ocular and inhalation exposure to printing workers may occur during printing and cleaning processes. The potential for inhalation exposure would be reduced by exhaust ventilation around the printing machines, and by the relatively low volume of use. Some further slow volatilization of the notified chemical from the print matrix may occur during storage of the printed material, and worker exposure would be reduced by good general ventilation in storage areas. Dermal and ocular exposure would be controlled by use of personal protective equipment (PPE) and safe work practices.

The notified chemical is a Class 3 flammable liquid, based on calculated data, but will not be introduced as the chemical itself. Inks containing it at up to 30% may also have flammable characteristics. Workplace controls to avoid fire or explosion may be needed to reduce the risk from flammability.

As the notified chemical is not classified as a hazardous substance, but analogue data suggests that it may have significant adverse health effects after repeated exposure (reproductive and developmental effects), this information should be communicated to users via the MSDSs for the ink products.

The risk to workers from the use of the notified chemical is not expected to be unacceptable under the conditions of use and controls in place to reduce exposure.

6.3.2. Public health
Giving the limited potential for public exposure to the notified chemical as the ink product containing the notified chemical will be only used in commercial/industrial settings, the notified chemical is not expected to pose an unacceptable risk to the 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 not be manufactured or reformulated within Australia. Therefore, release may only occur during transport and handling of the imported formulated products, and as such is not expected to be significant.

RELEASE OF CHEMICAL FROM USE
Some release is expected to occur during the printing process via cleaning and maintenance operations and small spills. It is expected these residues will be disposed of to landfill. The formulated products containing the notified chemical will be applied to substrate (such as vinyl, paper, mesh vinyl, shade cloth and other substrates which are capable of holding images) using industrial inkjet printers. The applied notified chemical is expected to be trapped in the matrix of the ink with other ingredients of the ink. However, some of the

notified chemical is expected to be released to air due to its high volatility (vapour pressure of 0.318 KPa at 25°C) and partially vented through an industrial extraction system.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical is expected to be disposed of to landfill and is expected to remain associated with the substrate to which it has been applied. Of the notified chemical applied to paper, 50% is expected to be recycled. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of toner from the fibres.

7.1.2 Environmental fate

Due to its high volatility, the notified chemical's potential for persistence in air and long range transport was assessed using "AOP Program (v1.92)". This estimates the half-life of the notified chemical in air, based on a 12 hour day, as being 3.7 h, which indicates that the notified chemical is expected to react rapidly with OH-radicals and therefore will not have the potential for long-range transport.

An analogue of the notified chemical has a high water solubility and low log Pow. It is therefore expected that a significant proportion of the notified chemical that is released to sewage treatment plants will remain in the treated effluent and be released to the environment.

In landfill the notified chemical is expected to degrade via biotic and abiotic processes over time to form predominantly simple organic compounds and water. Leaching of the notified chemical into water is likely due to its estimated high water solubility and low adsorption/desorption coefficient.

Based on the notified chemical's high solubility in water and low log Pow, the notified chemical is not expected to bioaccumulate.

7.1.3 Predicted Environmental Concentration (PEC)

Under a worst case scenario, it was assumed that 50% of the products containing ink will be recycled and released into sewers and there would be no removal of the notified chemical by the sewerage treatment plant. The resultant Predicted Environmental Concentration (PEC) in sewage effluent nationwide is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.92	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.45	µg/L
PEC - Ocean:	0.05	µg/L

7.2. Environmental effects assessment

Results for an analogue of the notified chemical from ecotoxicological investigations are summarised in the table below. Limited details of these studies were published.

Endpoint, Test species, Test	*Result*	*Assessment Conclusion*
Fish Toxicity (*Leuciscus idus*) Static Test	*subspicatus*) OECD 201 Inhibition of Bacterial Respiration OECD 209	
Daphnia Toxicity (*Daphnia magna*) OECD 202		
Algal Toxicity (*Scenedesmus*		

LC0 (96 h) > 2000 mg/L	EC10 (72 h) > 1000 mg/L	Not harmful
EC0 (48 h) >1000 mg/L	EC10 (72 h) > 1000 mg/L	Not harmful
Tadpole toxicity (*Rana brevipoda*)	LC50 (8300 – 22000) mg/L	Not harmful

The results of the ecotoxicity studies submitted indicated that the notified chemical is not expected to be harmful to aquatic organisms.

7.2.1 Predicted No-Effect Concentration

The lowest endpoint from ecotoxicological studies of an analogue to the notified chemical were used to calculate the PNEC. A conservative assessment factor of 1000 was used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
	1,000	mg/L
Assessment Factor	1,000	
PNEC:	1,000	µg/L

7.3. Environmental risk assessment

The Risk Quotient values have been calculated as follows:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.45	1,000	**$4.5x10^{-4}$**
Q - Ocean	0.05	1,000	**$5.0x10^{-5}$**

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be <<0.01 based on the above calculated PEC and PNEC. The Q value of <<1 indicates the notified chemical is not expected to pose an unacceptable risk to the aquatic environment from its proposed use pattern.

Based on the short half-life of the notified chemical in air, it is not expected to pose an unacceptable risk in this compartment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided, the notified chemical could not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not expected to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows under the ADG Code:
  - Class 3 – Flammable liquid, Packing Group III

Material Safety Data Sheet

- MSDS for inks containing the notified chemical should contain the following information:
  - Section 7 – Handling and Storage: “Avoid inhalation of product vapours or dust” or similar wording.

- Section 11 – Toxicological information. Chronic Exposure section "Based on analogue data, the ingredient Polyalkyleneglycol ethylmethylether may cause harm to the unborn child or risk of impaired fertility after repeated exposure" or similar wording.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced for use in the ink cartridges:
  - Local Exhaust extraction in printing area
  - Good general ventilation in storage areas for printed materials
  - Automated system for loading of cartridges

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced for use in the ink products:
  - Avoid contact with skin and eyes
  - Avoid inhaling fumes / vapours

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced for use, in the ink products:
  - Gloves
  - Respiratory protection if exposure to vapours from ink is expected

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

- Suppliers should evaluate the flammability characteristics of inks containing the notified chemical, and make appropriate recommendations for safe use via the MSDSs.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must 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(1) of the Act; if

- the importation volume exceeds one tonne per annum notified chemical;
- the notified chemical is imported in any form other than a component of printing ink at up to 30% concentration in sealed cartridges;
- the ink containing the notified chemical is used for printing in other than commercial facilities

or

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

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

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

Material Safety Data Sheet

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

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point 167.9°C at 101.3 kPa

Remarks Boiling point calculated using ACD/I-Lab service.

Density 908 kg/m^3 at 20°C

Remarks Estimated by Chemspider

Vapour Pressure

1. 230 – 1100 Pa at 20°C (analogue chemical)
2. 318 Pa (notified chemical)

Method
1. Result from a Concise International Chemical Assessment Document (CICADS) report. Method not reported.
2. Calculated using EPISuite v4.0

Remarks The calculated value of the vapour pressure of the notified chemical is consistent with that determined experimentally on the analogue chemical.

Test Facility

Water Solubility

1. Miscible with water (analogue chemical)
2. 76 g/L at 25°C (notified chemical)

Method
1. Result from a Concise International Chemical Assessment Document (CICADS) report. Method not reported.
2. Calculated from log Pow using WSKOW v1.41

Remarks The calculated value of the solubility of the notified chemical is consistent with that determined experimentally on the analogue chemical.

Test Facility

Partition Coefficient (n-octanol/water)

1. log Pow = -0.36 (analogue chemical)
2. log Pow = 0.01 (notified chemical)

Method
1. Shake flask. Result from a Concise International Chemical Assessment Document (CICADS) report.
2. Calculated using KOWWIN v1.67

Remarks The calculated value of log Pow of the notified chemical is consistent with that determined experimentally on the analogue chemical.

Test Facility

Adsorption/Desorption – screening test log Koc = 0.66 – 1 (notified chemical)

Method Calculated using KOCWIN v2.00 (EPISuite v4.0)
Remarks
Test Facility

Flash Point 53.8°C at 101.3 kPa

Method
Remarks Estimated by Chemspider
Test Facility

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 Male
Vehicle	None
Observation Period	72 hours 7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2.0	1.67	1.33	2.0	<7 days	0.0
Oedema	1.0	1.0	0.33	2.0	<7 days	0.0

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

Remarks - Results	Well-defined erythema was noted in all animals at 24 hrs and in 2/3 animals at 48 hr and in 1/3 animals at 72 hr. Slight oedaema noted in all animals at 24 hr, with very slight oedaema at 48 hr in 2/3 animals and 1/3 animals at 72 hr. The test substance is not classified as an irritant according to NOHSC Approved Criteria.
CONCLUSION	The notified chemical is irritating to skin.
TEST FACILITY	Safepharm (1997a)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
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
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, *E. coli*: WP2uvrA
Metabolic Activation System	Liver fraction (S9) from rats pre-treated with Aroclor 1254.
Concentration Range in Main Test	a) With metabolic activation: 50-5000 µg/plate b) Without metabolic activation: 50-5000 µg/plate
Vehicle	Distilled water
Physical Form	Liquid
Remarks - Method	No significant protocol deviations. The dose range was determined in a preliminary toxicity study on two strains. Positive control groups (S9): TA1537: 9-aminoacridine; TA98: 2-nitroquinoline-1-oxide; TA100, TA1535 and WP2 uvrA: N-ethyl-N'-nitro-N-nitrosoguanidine (ENNG). Positive controls (S9): All strains: 2-aminoanthracene. Negative (vehicle) control: distilled water

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>5000		Nil
Test 2	>5000	>5000		Nil
Present				
Test 1	>5000	>5000		Nil
Test 2	>5000	>5000		Nil

Remarks - Results

All positive control chemicals induced marked increases in mutation frequency. The test substance caused no visible reduction in the growth of bacterial lawn at any dose level. No significant increases in the frequency of revertant colonies were recorded for any bacterial strain at any dose level of test substance, both with and without S9.

CONCLUSION

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

TEST FACILITY

Safepharm (1997b)

BIBLIOGRAPHY

AIHA (1962), Reference from RTECS (Registry of Toxic Effects of Chemical Substances)

ILO (2007) International Labour Organization. Safework bookshelf v4, (2007). Glycol Ethers. Accessed through http://www.ilo.org/safework_bookshelf/english?content&nd=857171299

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

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 SIDS (2001). Dipropylene Glycol Methyl Ether (DPGME). SIDS Initial Assessment Report (for SIAM 12).

Safepharm (1997a). Hisolve EDM: Acute Dermal Test in the Rabbit. SPL Project Number 899/003. Safepharm Labs Ltd, Derby, UK. (unpublished study provided by notifier).

Safepharm (1997b). Hisolve EDM: Reverse Mutation Assay "Ames Test" using Salmonella Typhimurium and Escherichia Coli. SPL Project Number 899/004. Safepharm Labs Ltd, Derby, UK. (unpublished study provided by notifier).

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 >.

USEPA (2002) US Environmental Protection Agency. Chemical Categories Report (2002) Accessed at http://www.epa.gov/oppt/newchems/pubs/chemcat.htm