LTD/1027

6 December 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

S168746

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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
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

S168746

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Toxikos Pty Ltd of 293 Waverly Road, Malvern East VIC 3145

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 Name
CAS Number
Molecular Formula
Structural Formula
Molecular Weight
Spectral Data
Purity
Identity of hazardous/non-hazardous impurities
Identity of additives/adjuvants
Import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES

2. IDENTITY OF CHEMICAL

MARKETING NAME
S168746

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	HPLC, UV-Vis
Remarks	The notified chemical can be identified by HPLC or UV-Vis spectroscopy. All relevant data and spectra were supplied by the notifier.
TEST FACILITY	Analytical Sciences Group (2001)

3. COMPOSITION

DEGREE OF PURITY **Confidential**
>90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

4. INTRODUCTION AND USE INFORMATION

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

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

USE
S168746 is a dye used in preparations for ink-jet reprographic processes.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated

TRANSPORTATION AND PACKAGING
S168746 is imported into Australia in sealed ink-jet cartridges. The volume of a single coloured (non-black) cartridge ranges from 2-15 mL. Cartridges will be delivered to consumers by road transport.

5.2. Operation Description

No reformulation or repackaging of the product occurs in Australia. The product is delivered to the end-user as it is imported into Australia. The sealed ink-jet cartridge will be handled by service technicians or office workers replacing the spent cartridges in the printer.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours per day)*	*Exposure Frequency (days per year)*
Printer Service Technicians	1000	4	40
Distribution (Storage and Transport)	100	6	240
Office workers/consumers	10 000	<0.1	20

Exposure Details
The notified chemical is contained in sealed cartridges. The volume of the notified chemical in any single coloured (non-black) cartridge will range from 2-15 mL. Normal handling, involving replacement of the cartridge would not normally result in exposure. Exposure would only result if the cartridge were faulty or ruptured.

5.4. Release

RELEASE OF CHEMICAL AT SITE
No release is expected as reformulation of the ink containing the notified chemical will not take place in Australia.

RELEASE OF CHEMICAL FROM USE
Release of the ink to the environment is not expected under normal use as ink cartridges are sealed and designed to prevent leakage. However, if leakage or spill does occur, the ink will be contained with absorbent material that will be disposed of to landfill in the normal garbage. Environmental exposure will result from the disposal of the printed paper and discarded cartridges, as well as the possibility of accidental leakage during use. Ink residues contained in the empty cartridges and drums are expected to remain within these containers, although release could occur as a result of deterioration of the container. The worst case estimate of the amount of residue in the spent cartridge is 10%, assuming that the printer does not have individual colour wells. Annually, this would represent less than 20 kg of notified chemical. If the printer has individual colour wells, ink cartridges

will be replaced as required and there would be less residual ink in the cartridge.

Up to 99.9% of the notified chemical will be bound to the printed paper. This paper will either be disposed of to landfill, by incineration or it may be recycled. In the latter case, the ink will be removed by a de-inking process and the notified chemical will end up contained in the ink in the resultant sludge, which will be disposed of to landfill.

5.5. Disposal

Ultimately, the total import volume of the notified chemical will be disposed of to either landfill or incinerated.

5.6. Public exposure

The public will be exposed to the dye after use, when it is expected to be fixed to the paper. Limited exposure may occur while changing inkjet cartridges, however this will be relatively infrequent and should only result in very limited exposure.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Orange/Brown solid

Melting Point >300ºC

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Determined using metal block apparatus
TEST FACILITY Analytical Sciences Group (2001)

Density 1604.6 kg/m^3 at 20ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Measured using a Micrometrics Pycnometer 1330 TC, calibrated using glycerol.
TEST FACILITY Analytical Sciences Group (2001)

Vapour Pressure Not determined.

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Not likely to be volatile based on molecular weight and organometallic composition.

Water Solubility 300 g/L at 25ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Analytical Method: A6 Shake flask method, concentrations measured spectrophotometrically. No evidence of chemical instability of the test substance was found, indicating that the chemical is readily soluble.
TEST FACILITY Analytical Sciences Group (2001)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*50 ºC*	*days*
4	<10%	7

7	<10%	7
9	<10%	7

Remarks As less than 10% degradation occurred in the first 7 days, the study was terminated.
TEST FACILITY Analytical Sciences Group (2001)

Partition Coefficient (n-octanol/water) log P_{OW} at 20°C = <-4.0…

METHOD OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Analytical Method: Shake flask method with measurements in water made via spectrophotometry and comparison to calibration curve. The concentration in n-octanol was less than the detection limit. This result is very low and indicates that the chemical is hydrophilic.
TEST FACILITY Analytical Sciences Group (2001)

Adsorption/Desorption – screening test Not determined.

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
Remarks The notified chemical is unlikely to adsorb based on the chemical's water solubility but may do on account of its anionic character.

Adsorption/Desorption – main test Not determined.

Remarks Given that the substance is intended to be used as a dye and therefore has structural properties that favour fastness to paper, it is expected that the substance will adsorb to soil.

Dissociation Constant Not determined.

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks The chemical is a mixed Li/Na salt of a dye containing both carboxylic and sulfonic acid functionality. The former will become free acid at pH<5, while the latter will remain fully dissociated due to the strong acidity.

Particle Size Not available.

Remarks The notified chemical will be imported only as part of inkjet cartridge (liquid).

Flammability Limits Not flammable.

Autoignition Temperature Not available.

Explosive Properties Not explosive.

Reactivity Low.

Remarks The notified chemical was not changed significantly by storing at 54±2°C for 14 days when compared by HPLC. The appearance of the test substance did not change.
No instability of the substance was observed during water solubility tests.
No ageing of the substance was noticed during the measurement of surface tension.

ADDITIONAL TESTS

Surface Tension	72.43 mN/m at 25ºC
METHOD	OECD TG 115 Surface Tension of Aqueous Solutions. EC Directive 92/69/EEC A.5 Surface Tension.
Remarks	Concentration: 0.1g/100mL. No aging effect was noticed during measurement of surface tension. The results indicate that the substance is not surface active.
TEST FACILITY	Analytical Sciences Group (2001)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 … mg/kg bw	harmful
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation - adjuvant test/non-adjuvant test.	no evidence of sensitisation.
Genotoxicity - bacterial reverse mutation	inadequate evidence of non-mutagenicity

7.1. Acute toxicity – oral

TEST SUBSTANCE S168746

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain Rat/Spraque-Dawley CD.

Vehicle Distilled water.

Remarks - Method All animals were dosed once only by gavage, using a metal cannula attached to a graduated syringe. Dose volume was 10 ml/kg.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 female	2000	100%
2	3 female	200	0
3	3 male	200	0

LD50 Estimated to be in the range 300-500 mg/kg bw.

Signs of Toxicity Hunched posture, lethargy, diarrhoea, diuresis, pilo-erection, ptosis, splayed or tiptoe gait, decreased respiratory rate and laboured respiration were observed in the group dosed with 2000mg/kg. Hunched posture was noted in females treated at a dose level of 200 mg/kg. All animals treated at a dose level of 200 m/kg appeared normal throughout the study or one day after dosing.

Effects in Organs Abnormalities at necropsy of females treated at 2000mg/kg that died during the study were haemorrhagic lungs, dark liver, dark kidneys, yellow material present in the stomach, sloughing and/or yellow staining of the gastric mucosa, yellow staining of the non-glandular region of the stomach and slight haemorrhage of the small intestine. No abnormalities were noted at necropsy of animals that were killed at the end of the study.

Remarks - Results The surviving animals showed expected gains in bodyweight over the study period.

CONCLUSION The notified chemical is harmful via the oral route.

TEST FACILITY Safepharm Laboratories Limited (2001a).

7.4. Irritation – skin

TEST SUBSTANCE

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

Vehicle	Distilled water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.

RESULTS

Remarks - Results	Yellow coloured staining was noted at all treated skin sites throughout the study. The staining did not affect evaluation of skin responses. No evidence of skin irritation was noted during the study. No corrosive effects were noted. The test material produced a primary irritation index of 0.0 and was classified as non-irritant to rabbit skin according to the Draize classification scheme.
CONCLUSION	The notified chemical is non-irritating to skin.
TEST FACILITY	Safepharm Laboratories Limited (2001b).

7.5. Irritation - eye

TEST SUBSTANCE	S168746
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 male
Observation Period	72 hours
Remarks - Method	Initially, a single rabbit was treated. After consideration of the ocular responses produced in the first treated animal, two additional animals were treated. In order to minimise pain on application of the test material, one drop of local anaesthetic (Amethocaine hydrochloride 0.5%) was instilled into both eyes of these animals 1 to 2 minutes before treatment.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1	1	0.3	2	48	0
Conjunctiva: chemosis	0.3	0.3	0.3	1	24	0
Conjunctiva: discharge	0.3	0.3	0.3	1	24	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results	Yellow coloured staining of the fur was noted around all treated eyes throughout the study, and in two treated eyes one hour after treatment. The staining did not affect evaluation of ocular effects. No corneal effects were noted during the study. Iridial inflammation was noted in one eye one hour after treatment. No other iridial effects were noted. Moderate conjunctival irritation was noted in all treated eyes one hour after treatment with minimal to moderate conjunctival irritation at the 24-hour observation. One treated eye appeared normal at the 48-hour observation and two treated eyes appeared normal at the 72-hour observation.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Safepharm Laboratories Limited (2001c).

7.6. Skin sensitisation

TEST SUBSTANCE S168746

METHOD OECD TG 406 Skin Sensitisation .
EC Directive 96/54/EC B.6 Skin Sensitisation – Method B6.

Species/Strain Guinea pig/Dunkin Hartley

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal:
topical:

MAIN STUDY

Number of Animals Test Group: 10 Control Group: 5

induction phase Induction Concentration:
intradermal injection 5% w/w
topical application 50% w/w

Signs of Irritation Yellow coloured staining prevented evaluation of erythema at intradermal induction sights. Discrete or patchy erythema was observed on four control animals at 24 hours for both concentrations. Bleeding from the intradermal injection sites was noted in all test group animals at the 1-hour observation.

Yellow staining was noted at the topical induction sites of all test group animals at 1 hour and 24 hour observations but did not affect evaluation of skin responses. Moderate and confluent erythema and very slight oedema were noted at the topical induction sites of the test group animals. A hardened light brown scab was noted at the topical induction sites of three animals at the 24 hour observation. Residual test material was noted at the topical induction sites of all test group animals at the 1-hour observation. Discrete or patchy erythema was noted at the topical induction sites of control group animals.

CHALLENGE PHASE

1st challenge topical application: 25% w/w
topical application: 10% w/w

Remarks - Method

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	10%	0	0		
	25%	0	0		
Control Group		0	0		
		0	0		

Remarks - Results Yellow coloured staining was noted at the topical challenge sites of all test and control animals at the 24-hour and 48-hour observations. The staining did not affect evaluation of skin responses. No skin reactions were noted at the challenge sites of the test or control animals at the 24-hour or 48-hour observations for either the 25% w/w or 10% w/w concentration sites.

One control animal was found dead on Day 20. The death was thought not to be treatment related and the absence of this animal was considered not to effect the purpose or integrity of the study.

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

TEST FACILITY	Safepharm Laboratories Limited (2001d).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE	S168746
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, TA102. *E. coli*: WP2 uvrA.
Metabolic Activation System	Rat liver (S9)
Concentration Range in Main Test	a) With metabolic activation: 50, 150, 500, 1500, 5000 µg/plate. b) Without metabolic activation: 50, 150, 500, 1500, 5000 µg/plate.
Vehicle	Distilled water.
Remarks - Method	This study used the plate incorporation method. For azo compounds, mutagenicity may be more readily detected using the preincubation approach, which ensures maximum interaction between the tester strain, S9 and test chemical (Derelanko et al 1995). The preincubation step facilitates azo reduction and the detection of the resulting mutagenic aromatic amines (Prival and Mitchell 1982).
RESULTS	
Remarks - Results	No 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.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Safepharm Laboratories Limited (2001e).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE S168746

METHOD OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.

Inoculum	Centrifuged, washed and resuspended activated sludge from a predominantly domestic sewage treatment works
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	BOD – Hach manometric biochemical oxygen demand apparatus using potassium hydroxide solution. Bottle contents/change in chemical structure – high performance liquid chromatography.
Remarks - Method	The study consisted of 3 blanks, 3 test substance and 6 reference substance bottles. The concentration of S168746 in the test substance bottles was 100 mg/L

RESULTS

Test substance		*Sodium acetate*	
Day	*% degradation*	*Day*	*% degradation*
5	<5	5	57
9	<5	9	62
15	<5	15	68
20	<5	20	67
28	<5	28	67

Remarks - Results The sodium acetate standard attained greater than 60% biodegradation after 28 days, indicating the test conditions were valid.

CONCLUSION The test substance (S168746) is not readily biodegradable.

TEST FACILITY Brixham Environmental Laboratory (2001a)

8.2. Ecotoxicological investigations

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE S168746

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	215 mg $CaCO_3$/L
Analytical Monitoring	Spectrophotometric analysis
Remarks - Method	

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*

0	<0.24	20	0	0
120	130	20	0	0

EC_{50}	>120 mg/L at 48 hours
NOEC (or LOEC)	120 mg/L at 48 hours
Remarks - Results	The study was conducted in quadruplicate with 5 daphnia to each test bottle. No abnormal behaviour or mortality was observed in any of the test or control bottles.
CONCLUSION	The result indicates that the test substance is very slightly toxic to daphnia.
TEST FACILITY	Brixham Environmental Laboratory (2001b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will enter environmental compartments indirectly by disposal of waste paper (via recycling, landfill or incineration) and by direct release from discarded spent cartridges to landfill sites. Some waste paper may be disposed of directly to landfill with the notified chemical strongly bound to the paper. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified substance. Incineration of waste paper will destroy the compound with the generation of water vapour and oxides of carbon, nitrogen, and sulphur, and lithium and sodium. In addition to landfill, some of the ink printed on paper may enter the paper recycling process. During such processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. De-inking wastes are expected to go to trade waste sewers. Trade sources estimate the washing process will recover 30-60% of the total amount of ink and therefore at least 30% of the notified chemical in the recycled paper will be disposed of with sludge in landfill.

Based on the import volume, method of packaging and low concentration of the notified chemical in ink, release of the notified chemical to the environment is expected to be low but widespread. Waste from the recycling process includes sludge which is dried and disposed of to landfill, and little of the notified chemical is expected to partition to the supernatant water which is released to the sewer.

Although it is not considered to be readily biodegradable, biodegradation of the notified chemical is expected to eventually occur. The low octanol-water partition coefficient and high water solubility indicate the notified chemical will be predominantly distributed in water, where it will become diluted and dispersed and eventually partition to sediment, which may be assisted by its anionic character.

In addition, bioaccumulation is not expected due to the low log P_{OW}, indicating low lipid solubility.

9.1.2. Environment – effects assessment

The notified chemical is slightly toxic to daphnia. However, there will be limited release to water and a PNEC will not be derived.

9.1.3. Environment – risk characterisation

The new chemical will be used as an ingredient of printing ink formulations, and most will eventually be disposed of in landfill. The compound is not readily biodegradable (<5% over 28 days), and has a low partition coefficient (log P -4) and high water solubility (300 g/L), all indicating that most of the material would eventually partition to water.

The above considerations indicate minimal risk to the environment when the notified chemical is used as a component of ink in the manner and levels indicated.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

S168746 is imported in sealed cartridges as a component of a liquid ink. Although large numbers of workers may be involved in loading the ink cartridges into printers, occupational exposure is expected to be low. Contact with the dye is only likely to occur if the cartridge is faulty and ruptures. As the quantity of the ink in a cartridge is small (<15 ml) and the dye comprises <3.0% w/w of the ink, exposure is likely to be low even in the event of an accidental spill or leak. The notified chemical is designed to fix to paper during the printing process. The amount of dye per page of A4 black text is estimated to be between 0.1 and 1.0 mg.

9.2.2. Public health – exposure assessment

Public exposure is expected to be limited, as the dye is bound to the paper after use and is unlikely to be bioavailable. While changing inkjet cartridges, individuals may have limited dermal exposure to the notified substance. The potential for ingestion is limited as the inkjet cartridges are sealed prior to insertion in the printer. The small volume (2 to 15 mL) in each cartridge will also limit potential oral exposure.

9.2.3. Human health - effects assessment

S168746 is an azo dye that has high solubility in water, and low solubility in organic solvents. The octanol-water partition coefficient is significantly less than one. While these factors would mitigate against bioaccumulation of the compound, yellow staining of skin and organs in toxicity testing would seem to indicate some deposits in the cell cytoplasm. No staining of the urine or faeces was noted to indicate metabolism and removal of the dye.

In acute oral toxicity tests, rats were treated at concentrations of 2000 mg/kg and 200 mg/kg. At 2000 mg/kg, all rats died within one day of dosing. Symptoms of systemic toxicity observed in these rats included hunched posture, lethargy, diarrhoea, diuresis, pilo-erection, ptosis, splayed or tiptoe gait, decreased respiratory rate and laboured respiration. Abnormalities at necropsy included haemorrhagic lungs, dark liver, dark kidneys, yellow material present in the stomach, sloughing and/or yellow staining of the gastric mucosa, yellow staining of the non-glandular region of the stomach and slight haemorrhage of the small intestine. At 200 mg/kg, all animals survived to the end of the observation period, and no abnormalities were noted at necropsy. Hunched posture was observed in the three females in the 200 mg/kg dose group at 2 and 4 hours after dosing. The concluded estimate LD_{50} given in the test report cannot be supported however. The LD_{50} should be stated as >200 mg/kg but less than 2000 mg/kg. The NOAEL also cannot be determined from the data, but is <200 mg/kg for females, and >200 mg/kg for males.

The notified chemical was not shown to be irritating to the skin or eye. Although yellow staining of the skin prevented accurate evaluation of erythema following topical and intradermal induction, the compound was not found to be sensitising to guinea pig skin.

Azo compounds undergo enzymatic reduction *in vivo* involving cytochrome P450 (Ballantyne 1995). Methods used to test for mutagenicity need to take account of this biotranformation. Although some debate still exists on the most appropriate methods of ensuring reduction of the compound, a 30 minute pre-incubation step, the use of uninduced hamster liver S9 rather than Arachlor induced rat liver S9, and flavin mononucleotide rather then riboflavin are among the changes to the standard Ames method that have been recommended (Gatehouse et al, 1994, Prival and Mitchell, 1982). Not all these protocols were followed in testing this compound. Specifically, due to the use of the plate incorporation method, the claim of non-mutagenicity is not supported by this study.

According to NOHSC (1999), S168746 is classifiable as harmful, based on the acute oral toxicity LD_{50}<2000 mg/kg.

9.2.4. Occupational health and safety – risk characterisation

The most likely exposure route for the notified chemical is dermal. Staining of tissue during toxicity testing indicates that this chemical may penetrate the skin. S168746 belongs to a class of chemicals known to include many skin sensitisers. The possibility of skin sensitisation resulting from dermal contact with the notified chemical can therefore not be dismissed on the basis of a single negative test. However, the amount of the notified chemical to which a worker may be exposed is low, both because of the low volume involved in a likely contact scenario, and because the concentration of dye in the ink is low. Based on the low potential for worker exposure, the risk to workers may be considered to be low. Nevertheless, to minimise any risk, proper instruction in the handling of inks, particularly in clean-up procedures in the event of contact, should be given to workers via MSDS, labels and instruction manuals,

9.2.5. Public health – risk characterisation

As public exposure to the notified chemical is likely to be low, the risk to public health is also

expected to be low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). The classification and labelling details are: …

R22 Harmful if swallowed

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following hazard classification for the notified chemical:
  - Xn Harmful
- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 25% R22 Harmful if swallowed

CONTROL MEASURES

Occupational Health and Safety

- 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 NOHSC *Approved Criteria for Classifying Hazardous*

Substances, 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 into landfill.

Emergency procedures

- Spills/release of the notified chemical should be contained with absorbent material and transferred to a sealable waste container, and the resulting waste disposed of in landfill.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

Under Section 64(2) of the Act:

– if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

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