File No: STD/1136

June 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

AO-119-144

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 and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

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

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

AO-119-144

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Carter Holt Harvey Australia Pty Ltd (77 000 601 892)
Como Office Tower
644 Chapel Street
South Yarra 3141 VIC

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

Chemical identity
Composition
Detailed use
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(S)
None.

NOTIFICATION IN OTHER COUNTRIES
EU 2002

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
AO-119-144
The substance will be imported as a component of various inks and concrete mould-release formulations that are as yet undesignated.

METHODS OF DETECTION AND DETERMINATION

METHODS ^{1}H Nuclear Magnetic Resonance
UV/visible Spectroscopy
Infrared Spectroscopy

3. COMPOSITION

DEGREE OF PURITY
>80%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Notified chemical will be imported into Australia in 200L steel drums as a component of printing inks and concrete mould-release formulations. The drums will be transported directly by road from the port facility to various facilities in Australia for storage prior to use.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100-300	100-300	100-300	100-300	100-300

USE
The notified chemical will be used in printing inks and concrete mould-release formulations.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Not known at this stage.

TRANSPORTATION AND PACKAGING
200L steel drums.

5.2. Operation description

Inks
The drums containing the ink (90% of imported volume and containing <15% notified chemical) will be stored at a warehouse, and then delivered to the sites of use. Repackaging of the drums will not occur. The formulated inks are used by commercial printers to print documents such as magazines, labels and packaging materials. At the printing sites, the drums of formulated inks are decanted into a reservoir on the printing presses together with aliphatic and aromatic hydrocarbon solvents. The formulation containing the notified chemical is used to print documents such as magazines, labels and packaging materials.

Depending on the printing technique employed, the ink containing the notified chemical is transferred from the ink reservoir to the paper by a system of rollers. The image to be printed is covered with the ink by the machine and the inked image is rotated against the material to be printed. The metering and application of the ink onto the print rollers is conducted automatically.

When the printing job has been completed, the residual ink in the ink reservoirs is transferred back to the original container via an automated pumping system. The parts of the printing press that are covered with ink are wiped clean using cloths and solvents. The printing company through licensed waste disposal contractors disposes of the cloths and solvents.

Concrete mould-release formulations
The drums containing the concrete mould-release formulation (10% of imported volume containing <50% notified chemical) will be stored at a warehouse, and then delivered to the sites of use. At building/construction sites, a drum bung will be removed and a tap inserted and used to extract aliquots (typically 5 L) of the formulations containing the notified chemical. The decanted product will be applied to concrete mould-contact surfaces using either a brush or hand spray equipment. After the concrete sets, it is anticipated that a portion of the mould-release formulation will be absorbed into the concrete or moulds if the surfaces are absorbent. It is anticipated that the majority of the product will remain in the moulds and may be reused or discarded.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport/warehousing	10	4 hours/day	10 days/year
Printing workers	20	40 min/day	230 days/year
Building/construction workers	4000	2 hours/day	90 days/year

Exposure Details

Transport and warehousing

Transport and warehouse workers may come into dermal and ocular contact with the notified chemical through accidental leaks and spillages of the drums and containers.

Printing

Printing workers may come into dermal contact with the ink (<15% notified chemical) when decanting drums of ink into the reservoir of the printing machine. Splashing during transfer may also cause accidental ocular contact. However, the viscosity of the inks is such that splashes from the ink would not be expected to occur. When in operation, the printing machines are provided with guards and covers to catch any airborne ink such as aerosols being generated by the rotating parts. In some machines where solvents are employed, such as gravure, the printing presses will be designed with solvent extraction to remove any aerosol and solvent vapours. Where the risk of ocular exposure is greatest, the workers will use eye protection such as safety glasses. Printing machine operators will be be provided with overalls covering the arms and legs to reduce dermal exposure. The overalls are laundered weekly. After application and once dried, the ink containing the notified chemical is cured into an inert matrix and as such not bioavailable and able to penetrate biological membranes.

Building and construction

Building and construction workers may come into dermal and accidental ocular contact with the notified chemical when removing the drum bung and inserting the tap, and when applying mould-release formulation. The tap will be used to fill receptacles (such as an empty paint can or spray equipment reservoir) with the formulation. After decanting, the mould-release formulation is applied to the surface of the mould immediately prior to pouring the concrete. Application of the formulation to the concrete will be typically performed with a paintbrush and rubber gloves will be worn to limit dermal exposure. Alternatively, trained workers using a facemask, goggles and gloves worn to minimise exposure may use hand-spraying equipment.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Environmental release of the notified chemical is unlikely during importation, storage and transportation. Accidental spills, leaks and catastrophic mechanical failure during a transport accident are the most likely reasons for environmental release. Engineering controls, e.g., drum specifications, and emergency clean-up procedures, i.e., spill response instructions on Safety Data Sheet and label, will limit the impact on the environment of such incidents. The drums containing the ink and concrete-mould formulations will be transported directly from the port facility to various facilities in Australia for storage prior to use.

RELEASE OF CHEMICAL FROM USE

Printing inks

This use pattern comprises approximately 90% of the total import quantity of the notified chemical (<270 tonnes per annum). There is limited potential for environmental release of the notified chemical during printing operations, with releases associated with the use of the printed-paper articles and disposal of wastes to landfill and incinerator. After application, the notified chemical will be cured and bound to the paper surface and not available for dissolution or leaching to the environment.

Concrete mould-release formulations

This use pattern comprises approximately 10% of the total import quantity of the notified chemical (<30 tonnes per annum). At building sites, the notified chemical will be applied to timber surfaces of

concrete moulds by brush or low-pressure sprayer. It is anticipated that the notified chemical will form a hydrophobic surface on the mould with little adhering to wet concrete. For this use pattern, approximately 99.5% of the notified chemical (<29.85 tonnes per annum) is expected to adhere to the mould material and 0.5% (0.15 tonnes per annum) onto or into the concrete surface where it is likely to remain. Over time, exposed concrete surfaces may leach the notified chemical if in contact with rainfall or water, however, the majority of the moulded concrete will be used internally, covered by plasterwork, decorative cladding and decorative coatings. Overspray during application may potentially comprise <5% of the notified chemical used (<1.5 tonnes per annum). The overspray would likely fall to drop sheets, hardstand or ground. Brushes, mould materials and emptied pails containing residues of the products containing the notified chemical will likely be sent to landfill for disposal. The use pattern at building sites would be widespread and diffuse in Australia. The notified chemical is not expected to react with the concrete and will be stable.

5.5. Disposal

Printing inks

A small amount of ink is wasted during the start-up of printing presses. This waste is applied to paper that is discarded as waste paper for recycling. Cleaning of printing presses and other equipment results in a limited amount of solvent-based waste, which is collected by licensed contractor for solvent recovery and incineration of residue. Emptied containers will be discarded with the containers to container/metal recycling facilities or washed and sent to landfill with the washings being collected for solvent recovery.

Eventually, most of the notified chemical will be either sent to land fill or sent for recycling in the paper products. Recycling may take place in a number of centres throughout Australia. During the paper recycling process, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. 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 or incinerated. However in this case, a greater proportion can be expected to partition to the sludge compartment due to the very low water solubility of the notified chemical.

Concrete mould-release formulations

After use, most (<29.85 tonnes per annum) of the notified chemical will eventually be disposed of with discarded mould materials to landfill. Residual product in emptied imported containers, estimated by the notifier to comprise <50 kg of the notified chemical, will mostly be collected by drum reconditioning contractors and the chemical residue would be collected and incinerated or sent to land fill.

5.6. Public exposure

Printing inks

The printing inks containing the notified chemical will be used only in large printing houses. Public exposure to printed articles will be widespread, however, the notified chemical will be immobile within a matrix and thus will not be bioavailable.

Concrete mould-release formulations

Public exposure to the concrete mould-release formulations is not expected. It is anticipated that <1% of the product (containing <50% notified chemical) would migrate from the mould into the concrete. Leeching of the notified chemical from the concrete, however, is not expected. Public exposure to the notified chemical will be further reduced as the treated concrete is typically covered when construction is complete.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Amber liquid

Freezing Point <-20ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks The notified chemical is a liquid at room temperature.

TEST FACILITY SPL (2002a)

Boiling Point Not determined

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Sample decomposes at ~368°C
TEST FACILITY SPL (2002a)

Density 0.89 kg/m^3 at 20°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Pycnometer method.
TEST FACILITY SPL (2003a)

Vapour Pressure 3.0 x 10^{-7} kPa at 25°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Vapour pressure balance. Measurements were made within the range 70-80°C. The test material did not change in appearance during the test period. The notified chemical is very slightly volatile (Mensink *et al*., 1995).
TEST FACILITY SPL (2003b)

Water Solubility 6.01 x 10^{-2} mg/L at 20°C (estimated)

METHOD EC Directive 92/69/EEC A.6 Water Solubility and estimated using WSKOW v.1.40. (Syracuse Research Corporation).
Remarks Flask Method. Preliminary and definitive tests were performed. For the latter, test material (approximately 0.7 g) was added to 1 L water and shaken (30°C). After standing for >24 h at 20°C, the solution was analysed by GC. Water solubility was estimated at 1.38 x 10^{-3} g/L However, as residual test material remained adhered to the glass containers and when shaken in water it formed a cloudy emulsion, the test method was considered invalid and an overestimate of water solubility.

Using WSKOW, water solubility was estimated to be 6.01 x 10^{-2} mg/L, based on the analysis of 7 components. Using this method, SPL (2003c) reported a water solubility at 25°C of 3.64 x 10^{-5} mg/L. SPL (2004d) indicated that at test concentrations >0.2 mg/L, the notified chemical formed a dispersion in the test substance. The notified chemical is estimated to be only very slightly soluble in water (Mensink *et al*., 1995).
TEST FACILITY SPL (2002a)

Hydrolysis as a Function of pH

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

pH	*T (°C)*	*$t_{½}$ years*
4	50	>1
7	50	>1
9	50	>1

Remarks Test solutions (0.6 mg/L nominal) were prepared with the aid of co-solvent (tetrahydrofuran, 1%) and no undissolved material was present in the test solutions. Analysis of test solutions by GC indicated that the test compound achieved <10% hydrolysis after 5 days at 50°C, equivalent to a half life of >1 year at 25°C. The notified chemical potentially hydrolyses but is prevented by very low water solubility. The notified chemical is estimated to be only slightly hydrolysing. The aquatic ecotoxicity tests reports marked loss of the test material after 24 – 96 hours due to abiotic processes.
TEST FACILITY SPL (2003a)

Partition Coefficient (n-octanol/water) log Pow = >6.20 at 20ºC

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks HPLC Method. Preliminary (visual assessment based on approx. solubility in octanol and water) and definitive tests were performed. Test material (1.06 g) was diluted to 100 mL with methanol. The test material eluted after the 6 reference substances used.
TEST FACILITY SPL (2002a)

Adsorption/Desorption – screening test log K_{oc} >5.63 at 30°C

METHOD EC Directive 2001/59/EC C.19 Absorption Co-efficient of Annex V
Remarks HPLC screening method. Test material (0.25 g) was dissolved in 50 mL methanol. The test material eluted after the 13 reference substances used. The test material is estimated to be immobile in soil (FAO, 2000).
TEST FACILITY SPL (2003a)

Dissociation Constant Not determined

Remarks The notified chemical does not contain structural groups that undergo dissociation.

Particle Size Not applicable (liquid)

Flash Point 98ºC at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Closed cup.
TEST FACILITY SPL (2002b)

Flammability Limits Not flammable

Remarks Based on the flash point of 98°C the notified chemical is not classified as flammable according to the Australian Dangerous Goods Code (ADG 1998).

Autoignition Temperature 346ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks None.
TEST FACILITY SPL (2003b)

Explosive Properties Predicted negative.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks No chemical groups present that would imply explosive properties.
TEST FACILITY SPL (2003b)

Reactivity

Remarks The chemical is is predicted to be stable under normal environmental conditions.

Surface Tension 59.4 mN/m at 21ºC

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Mean concentration: 3.28 x 10^{-4} g/L. Based on use of an interfacial tension balance, the test material is a surface-active material.
TEST FACILITY SPL (2003a)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rat, acute inhalation LC50	not performed
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 90 days.	NOEL 50 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical.

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/Crl: CD (SD) IGS BR
Vehicle	None.
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	There were no signs of systemic toxicity.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	None.

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

TEST FACILITY — SPL (2002c)

7.2. Acute toxicity – dermal

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain	Rat/Crl: CD (SD) IGS BR
Vehicle	None.
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	There were no signs of local toxicity.

Signs of Toxicity - Systemic	There were no signs of systemic toxicity. One female showed a bodyweight decrease in the first week of the study but expected body weight gain during the second week. All other animals showed expected bodyweight gains throughout the study.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	None.

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

TEST FACILITY SPL (2004a)

7.3. Acute toxicity – inhalation

The test was not conducted. The notified chemical is a non-volatile liquid hence is not expected to be an inhalation hazard when imported as a component of a liquid formulation.

7.4. 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
Vehicle	None.
Observation Period	72 hours
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	0.3	0.7	0.7	2	48 hours	0
Oedema	0.3	0.3	0.3	2	24 hours	0

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

Remarks - Results	Area of test site: dorsal/flank region. Well-defined erythema and slight oedema was observed in all test animals at the 1-hour observation period, which resolved over 24 to 48 hours.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY SPL (2002d)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical.

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
Observation Period	72 hours
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			
Conjunctiva: redness	0	0.3	0.3	2	24 hours	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Conjunctiva: discharge	0	0.3	0	2	24 hours	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks – Results

Minimal to moderate conjunctival irritation was noted in all animals one hour after treatment with minimal conjunctival irritation in 2 animals at the 24-hour observation period. No signs of irritation were observed in one animal at 24 hours. No signs of irritation were observed in any animal at the 48-hour observation period.

CONCLUSION

The notified chemical is slightly irritating to the eye.

TEST FACILITY

SPL (2002e)

7.6. Skin sensitisation

TEST SUBSTANCE

Notified chemical.

METHOD

Magnusson and Kligman maximisation method
OECD TG 406 Skin Sensitisation
EC Directive 96/54/EC B.6 Skin Sensitisation

Species/Strain

Guinea pig/Dunkin Hartley

PRELIMINARY STUDY

Maximum Non-irritating Concentration:
Intradermal: Not determined. At 1% *v/v* in arachis oil BP, moderate and confluent erythema was seen at injection sites, persisting for >72 hours.
Topical: Not determined. At 25% *v/v* in arachis oil BP, discrete or patchy erythema was seen up to 24 hours.

MAIN STUDY

Number of Animals

Test Group: 10 Control Group: 5

INDUCTION PHASE

Induction Concentration:
intradermal: 1% *v/v* in arachis oil BP
topical: undiluted

Signs of Irritation

Intradermal injection: Moderate and confluent erythema was seen at 24 hours and 48 hours in all treated animals. Discrete and patchy erythema was seen at 24 hours and 48 hours in all control animal receiving 100% arachis oil BP

Topical: Staining was noted at the topical induction site of all test group animals, lasting for 2 hours, but did not affect the evaluation of skin responses. Moderate and confluent erythema, with slight oedema, was seen in every test group animal at 2 hours. Bleeding was noted in three test group animals at the 2-hour observation. Discrete or patchy to moderate and confluent erythema, without oedema, was seen in every test group animal after 24 hours. Small superficial scattered scabs were noted in one test group animal. No reactions were seen for any animals receiving the control dose.

CHALLENGE PHASE

1st challenge	intradermal: not conducted topical: 75% *v/v* in arachis oil BP – right flank 50% *v/v* in arachis oil BP – right flank
Remarks - Method	Erythema and oedema were assessed 2 hours after topical induction, in addition to the usual assessment after 24 hours. Both 75% and 50% concentrations of the notified chemical were used in the topical challenge phase to ensure that the maximum non-irritant concentration was used in the study. Test sites were not pre-treated with sodium lauryl sulfate before topical induction.

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	75% (right flank)	1	0	-	-
	50% (left flank	0	0	-	-
Control Group	0	0	0	-	-

Remarks - Results	The slight erythema observed in one animal receiving a challenge dose of 75% at the 24 hour observation period, but not the 48 hours observation period, was most likely residual erythema caused by irritation.

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

TEST FACILITY SPL (2002f)

7.7. Repeat dose toxicity

TEST SUBSTANCE Notified chemical.

METHOD	OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Crl:CD (SD) IGS BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Arachis oil BP
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10/sex	0	0
II (low dose)	10/sex	5	0
III (mid dose)	10/sex	50	0
IV (high dose)	10/sex	1000	0

Mortality and Time to Death

All animals survived until the end of the study.

Clinical Observations

Increased salivation was detected up to one hour after dosing for animals of either sex treated with 1000 mg/kg bw/day from day 14 onwards. This is commonly observed following oral gavage administration of a slightly irritant or unpalatable test material. Males treated with 50 or 1000 mg/kg bw/day showed a statistically significant increase in sensory reactivity parameters. These were attributed to abdominal discomfort associated with the gavage procedure.

Males treated with 5 and 50 mg/kg bw/day showed a statistically significant ($p<0.05$) increase in bodyweight gain during week 2 compared to controls (15% and 19% respectively) with all other weekly bodyweight gains not significantly different from controls. In the absence of a dose-related response, or findings in other weeks, this is considered not to be of toxicological significance.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Blood chemistry analysis revealed that males treated with 1000 mg/kg bw/day showed statistically significant increases ($p<0.05$) in cholesterol (17%) and creatinine (8%) levels. In the absence of a dose-related response this is considered not to be of toxicological significance.

Males treated with 1000 mg/kg bw/day showed a statistically significant decrease in erythrocyte count ($p<0.05$, 4%). In the absence of any other haematological changes, and given the marginal nature of the decrease, this is considered not to be of toxicological significance.

Effects in Organs

The following effects were observed in the 1000 mg/kg bw/day group:

- increased absolute spleen weight ($p<0.05$, 20%) in males.
- increased relative kidney weight ($p<0.01$, 9%) in females
- increased absolute ($p<0.01$, 22%) and relative adrenal weight ($p<0.01$, 20%) in females.

The toxicological significance of these findings is uncertain as there were no supporting histopathology findings.

In the liver, the following effects were observed:

- increased absolute liver weights in males ($p<0.001$, 36%) and females ($p<0.001$, 24%), and
- increased relative liver weights in males ($p<0.001$, 28%) and females ($p<0.001$, 22%).

A marginal effect on hepatocyte size was observed in females treated with 1000 mg/kg bw/day ($p<0.05$) with a few animals from this group exhibiting centrilobular hepatocyte enlargement.

Remarks – Results

The most marked changes occurred in the liver of animals in the 1000 mg/kg bw/day group. The elevated relative and absolute liver weights in male and female rats are suggestive of an adaptive response in the liver to the notified chemical in the high dose treatment group. Animals in the 1000 mg/kg bw/day also showed increases in spleen, kidney and adrenal weight. None of these changes were observed in the 50 mg/kg bw/day group.

CONCLUSION

The No Observed Effect Level (NOEL) in male and female rats was established as 50 mg/kg bw/day in this study on the basis of both relative and absolute weight changes in the liver at 1000 mg/kg bw/day.

TEST FACILITY SPL (2004b)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical.
METHOD	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
Metabolic Activation System	S9
Concentration Range in Main Test	a) With metabolic activation: 50-5000 µg/plate b) Without metabolic activation: 50-5000 µg/plate
Vehicle	Acetone
Remarks - Method	No *E. coli* strain was used, and thus this test may not detect certain oxidizing mutagens, cross-linking agents and hydrazines (OECD TG 471).

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 µg/plate	>5000 µg/plate	≥5000 µg/plate	negative
Test 2	>5000 µg/plate	>5000 µg/plate	≥5000 µg/plate	negative
Present				
Test 1	>5000 µg/plate	>5000 µg/plate	≥5000 µg/plate	negative
Test 2	>5000 µg/plate	>5000 µg/plate	≥5000 µg/plate	negative

Remarks - Results	Negative controls were similar to historical values. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SPL (2002g)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Lymphocytes cultured from the blood of a suitable volunteer
Metabolic Activation System	S9
Vehicle	Acetone
Remarks - Method	2500 µg/ml was used as the maximum dose due to precipitation at 5000 µg/ml.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 39, 78.1, 156.25, 312.5*, 468.75*, 625*	24 hours	24 hours
Test 2	0*, 78.1, 156.25, 312.5, 625*, 1250*, 2500*	4 hours	24 hours
Present			
Test 1	0*, 78.1, 156.25, 312.5, 625*, 1250*, 2500*	24 hours	24 hours
Test 2	0*, 78.1, 156.25, 312.5, 625*, 1250*, 2500*	4 hours	24 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	Not performed	Up to 39% mitotic inhibition	>2500 µg/plate	negative
Test 2	Not performed	Up to 14% mitotic inhibition	>2500 µg/plate	negative
Present				
Test 1	Not performed	Negligible mitotic inhibition	>2500 µg/plate	negative
Test 2	Not performed	Up to 22% mitotic inhibition	>2500 µg/plate	negative

Remarks - Results

The notified chemical did not induce a statistically significant increase in the frequency of cells with chromosomal aberrations in either the absence or the presence of a liver enzyme metabolic system in either of two separate experiments.

Treatment with positive control substances induced distinct increases in cells with structural chromosomal aberrations.

CONCLUSION

The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY

SPL (2004c)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD
- Inoculum: Mixed culture of activated sewage sludge micro-organisms (Severn Trent Water plc sewage treatment works); tripled rinsed; suspended solids 3.0 g/L prior to use.
- Exposure Period: 28 days
- Auxiliary Solvent: None
- Analytical Monitoring: CO_2 in produced gas and dissolved organic carbon in solution
- Remarks - Method: Test material was dispersed directly in the culture medium and subjected to ultrasonication (30 mins) prior to dispersal in inoculated culture medium. Bottles were sealed and CO_2-free air bubbled into the stirred solutions and maintained in the dark. Initial test material concentration was 12.8 mg/L (10 mg C/L). The CO_2 produced was captured and analysed approximately daily. Test temperature 21°C. Each test vessel was inoculated to give a final concentration of 30 mg suspended solids/L. Test solutions pH range: 7.4-7.5.

RESULTS

Test substance (12.8 mg/L)		*Sodium benzoate (17.1 mg/L; 10 mg C/L)*	
Day	*% Degradation*	*Day*	*% Degradation*
1	0	1	13
2	19	2	38
6	37	6	45
12	40	12	55
16	58	16	73
28	60	28	92

- Remarks - Results: All test validation criteria were met. The reference substance (sodium benzoate) degraded by 92% after 28 days confirming the suitability of the inoculum and test conditions. In the toxicity control, the test material attained 79% degradation by day 28 confirming that the test substance was not toxic to the sewage micro-organisms used in the study.

CONCLUSION: The test material achieved 60% degradation after 28 days; however, it was not readily biodegradable under the conditions and the 10 day window criterion for this test.

TEST FACILITY: SPL (2002h)

8.1.2. Bioaccumulation

- Remarks - Results: Not determined. The notified chemical has an affinity for lipids and may potentially be capable of crossing biological membranes; however, the limited potential for release to water indicates a low potential for accumulation in aquatic organisms.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test - Freshwater/semi-static.

Species Rainbow trout *Onchorhynchus mykiss.* Juvenile 3.6 cm long, 0.57 g. Loading rate 0.29 g bodyweight/L

Exposure Period 96 hours

Auxiliary Solvent Acetone

Water Hardness 100 mg/L as $CaCO_3$

Analytical Monitoring GC (LOQ 0.0035 mg/L). Test solution samples were analysed at 0, 24, 48, 72 and 96 hours.

Remarks – Method At concentrations greater than 0.2 mg/L, the test substance formed a dispersion in the test solution. Stock solution (200 mg/10 mL solvent) was dispersed in dechlorinated tap water to give the nominal test concentration made up to 22 L. Test temperature: 14°C. DO range: >9.8 mgO_2/L. pH: 7.5-8.0. Photoperiod: 16 hours light and 8 hours dark. Effects were monitored at 3, 6, 24, 48, 72 and 96 hours.

In a preliminary stability test, the test material was unstable in water and acetone after storage in sealed glass vessels at ambient temperature in light and dark conditions for 24 hours. Under these conditions, stability was also assessed without mixing (sonication) and analytical testing of the unsonicated stability vessel solution showed no evidence of insolubility or adherence to glass. Stability was found to be directly proportional to storage temperature. The analytical method gave low recoveries (approximately 50%) but was considered by the laboratory to be sufficiently precise for the purposes of the test. All test sample results were corrected for mean procedural recovery applicable to each test sample period. Centrifuged test solutions showed much lower concentrations than uncentrifuged samples, indicating that the test substance was in a dispersion, separate phase (eg. fine globules) or settled form (undissolved). The test substance concentration was stable for the test period of renewal only in the centrifuged samples but reduced over time in the untreated solutions.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Solvent control	<LOQ	20 (2 replicates of 10)	0	0	0	0	0
0.20	0.29	20 (2 replicates of 10)	0	0	0	0	0

LC50 >0.045 mg/L at 96 hours (time-weighted mean)

NOEC 0.045 mg/L at 96 hours (time-weighted mean)

Remarks – Results An estimate of the LC50 value was made based on the inspection of the mortality data.

The test material was unstable during the test, with marked reduction in test material concentration after the period of media renewal (24 hour). The reason for this was not determined.

Bioaccumulation of the test substance into test organisms may also have occurred during the test. Exposure concentrations were calculated using mean measured values of the centrifuged samples.

CONCLUSION The test material was not toxic to fish up to the mean measured test concentration of ≤0.045 mg/L, or conversely up to the limit of its solubility (approximately 6 x 10^{-2} mg/L).

TEST FACILITY SPL (2004d)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test – freshwater/semi-static.

Species *Daphnia magna* (<24 hours old)

Exposure Period	48 hours
Auxiliary Solvent	Acetone
Water Hardness	250 mg/L as $CaCO_3$
Analytical Monitoring	GC (0, 24 and 48 hours)
Remarks - Method	Preliminary and definitive tests were conducted. Test temperature: 21°C. Photoperiod: 16 hours light and 8 hours dark. Effects were monitored at 24 and 48 hours. Test aquaria: 250 mL glass beakers.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Solvent control	<LOQ	40 (4 replicates of 10)	0	0
0.20	0.20	"	0	0

EC50	>0.044 mg/L (time-weighted mean) at 48 hours
NOEC	0.044 mg/L (time-weighted mean) at 48 hours
Remarks - Results	As above for the fish toxicity test, the test material was unstable and there was a marked decline in concentration over a 24 hour period when test solutions were replaced. Unlike in the fish test, the centrifuged samples were not stable for the duration of the test solution renewal period. Test values are presented on a time-weighted average basis of centrifuged samples.

CONCLUSION The test material was not toxic to *Daphnia magna* at the time-weighted mean concentration tested (0.045 mg/L), or conversely up to the limit of its solubility (approximately 6 x 10^{-2} mg/L).

TEST FACILITY SPL (2004e)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	Freshwater green algae (*Scenedesmus subspicatus*)
Exposure Period	72 hours
Concentration Range	Nominal: 0.20 mg/L Actual: 0 hours = 0.2 mg/L, 72 hours = 0.01 mg/L.
Auxiliary Solvent	Acetone
Water Hardness	Not reported
Analytical Monitoring	GC (0 and 72 h; samples with and without centrifugation).
Remarks – Method	Preliminary and definitive tests were performed. Test material was dissolved in acetone to give a 20 mg/10 mL solvent stock solution. An aliquot was dispersed in algal suspension to give the required test concentration of 0.20 mg/L. Cell counts were made using a Coulter multisizer particle counter. Continuous illumination (7000 lux). Initial cell density: approximately 10^4 cpm. Final cell density: approximately 5.5 x 10^5 cpm. Test pH: 7.4-7.9.

RESULTS

Biomass		*Growth*	
NOEC mg/L at 72 h	*EbC50 mg/L*	*NOEC mg/L at 72 h*	*ErC50 mg/L*
0.054	>0.054	0.054	>0.054

Remarks - Results	As seen in the fish and *Daphnia* toxicity tests, there was a marked decline in concentration over the duration of the test (ie. 5-6% of nominal after 72 hours). Test results are presented as the geometric mean measured test concentration. No inhibition was seen in the tests.
CONCLUSION	The test material was not toxic to freshwater green algae at the concentration tested (geometric mean 0.054 mg/L), or conversely up to the limit of its solubility (approximately 6 x 10^{-2} mg/L).
TEST FACILITY	SPL (2004f)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test and EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Mixed culture of activated sewage sludge micro-organisms (Severn Trent Water sewage treatment works).
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L
Remarks – Method	Test material was added to water and subjected to ultrasonication. Synthetic sewage (16 mL), activated sewage sludge (200 mL) and water were added to a final volume of 500 mL to give the required concentration of 1000 mg/L. Test temperature: 21°C. pH: 8.0. Hardness: approximately 100 mg/L. The rate of respiration was determined after 30 mins and 3 hours contact time and compared to data for the control and reference material (3,5-dichlorophenol). The EC50 values were calculated from a graphed line-of-best fit equation.
RESULTS	
EC50	>1000 mg/L (nominal) after 3 hours
NOEC	1000 mg/L (nominal) after 3 hours
Remarks – Results	At the test concentration, oily globules of the test material were visible on the surface and dispersed throughout the test media. The reference material gave a 3 hour EC50 of 12 mg/L confirming the suitability of the test conditions. Toxicity to sewage micro-organisms was not evident in the ready biodegradability test performed using the notified chemical.
CONCLUSION	The test material was not toxic to the sewage sludge micro-organisms under the conditions of the test.
TEST FACILITY	SPL (2003c)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release of the notified chemical during use as a concrete mould-release formulation or ink is likely to result in very limited release of the notified chemical to the environment. The majority will eventually be sent to landfill for disposal or incinerator for destruction. A fraction of the notified chemical may be released as a result of spills/leaks and drips to pavement or ground during application; however, these would likely be cleaned up and no predicted environmental concentration (PEC) of the notified chemical in soil or water could be derived. In landfill or soil, the notified chemical is likely to be degraded over time to water and oxides of carbon. It is expected to be hydrolytically stable and unlikely to be mobile based on its very low water solubility and would have a high affinity to soil organic matter based on its high partition coefficient (K_{oc}). Incineration of the notified chemical will likely reduce the compound to simpler compounds of water and oxides of carbon. The notified chemical has an affinity for lipids and may potentially be capable of passing biological membranes; however, the limited potential for environmental release indicates a low potential for accumulation in aquatic organisms.

9.1.2. Environment – effects assessment

Aquatic ecotoxicity data are available for 4 taxonomic groups, i.e. freshwater species. The disperse nature and instability of the test substance created difficulties in performing and interpreting the ecotoxicity test results. No toxicity was evident at the concentrations tested (nominally 0.2 mg/L). Test concentrations declined over time and consequently test results were reported as time-weighted average or similar values. The lowest available L(E)C50 value was >0.045 mg/L (NOEC 0.045 mg/L). A predicted no effect concentration of >0.45 μg/L has been derived by dividing the lowest EC50 value by a safety factor of 100; however, this is considered a conservative estimation as this was the highest concentration tested.

9.1.3. Environment – risk characterisation

The use pattern for the notified chemical will result in very limited potential for environmental release to the aquatic environment. In addition, the notified chemical has a very low water solubility and is unlikely to release to waters but will partition to sludge, sediments and soils. In the sewer or aquatic environments, the notified chemical is likely to degrade over time due to abiotic and biotic processes. Most of the notified chemical will, after use, be sent with waste materials (paper, timber) to landfill or incinerator and eventually forming water and oxides of carbon.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Dermal contact will be the main route of occupational exposure to the notified chemical although inadvertent ocular exposure via incidental splashes and spills during decanting and use of the ink and mould-release formulations may occur.

Transport and warehousing

Exposure to the notified chemical is not expected during transport and warehousing. However, transport and warehousing workers may come into dermal and ocular contact with the notified chemical through accidental leaks and spillages of the drums and containers.

Inks

Printing workers will use PPE such as wear gloves and overalls however there may still be dermal exposure to the ink (<15% notified chemical) when decanting drums of ink into the reservoir of the printing machine. The printing machines are provided with guards and covers to minimise exposure to airborne ink. Where this is not sufficient, local exhaust ventilation and/or eye goggles will be provided to limit the exposure.

Mould-release formulations

Dermal and ocular exposure to the concrete mould-release formulation (<50% notified chemical)

may occur due to splashes and spills when fitting the tap to the drum, decanting the product, or during manual painting. Gloves will limit dermal exposure. When hand spraying equipment is used, exposure will be limited through the use of face masks, goggles and gloves.

9.2.2. Public health – exposure assessment

Inks

The printing inks will be used only in large printing houses. Public exposure to printed articles will be widespread, however the notified chemical will be bound to the printed page, and thus will not be bioavailable.

Mould-release formulations

Public exposure to the concrete mould-release formulations is not expected. Less than 1% of the formulation would migrate from the mould into the concrete, and leeching from the concrete is not expected. Also, exposure to the concrete will be low, as it is usually covered over when construction is complete.

9.2.3. Human health – effects assessment

The notified chemical is of low toxicity via oral or dermal exposure. There was no evidence of any genotoxic effects. The notified chemical is slightly irritating, both to the skin, with short-lived moderate erythema and oedema was seen, and to the eye, where it caused transient redness and discharge of the conjunctiva. The 90-day oral repeat dose toxicity test revealed changes, related to organ weights and blood chemistry, in a number of rats treated at 1000 mg/kg bw/day, which were likely adaptive changes to the notified chemical. Thus, the oral NOEL in males and females was established as 50 mg/kg bw/day.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low, based on the non-hazardous nature of the chemical.

9.2.5. Public health – risk characterisation

The public health risk presented by the notified chemical is expected to be low, based on the non-hazardous nature of the chemical, and low exposure to the chemical.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

The notified chemical is not classified as hazardous to human health using the GHS. Environmental classification of the notified chemical using the GHS was not possible as aquatic toxicity test results were inconclusive.

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 as a component of ink for commercial printing, and in concrete mould-release formulations.

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 2003). 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 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

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.

Environment

Emergency procedures

- Spills/release of the notified chemical should be handled by applying absorbent material (eg. paper towel, sand, soil) to the spill. Transfer the spillage to labelled waste containers for disposal. Do not allow spilled materials or washings to enter drains, surface water or groundwater.

Disposal

- The notified chemical should be disposed of by incineration in accordance with waste disposal regulations.

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:

(1) Under Section 64(1) of the Act; if
- the notified polymer is used in applications other than as a component of an ink or a concrete mould-release formulation; or
- any manufacture of the notified chemical is expected to occur; or
- further toxicological data on the notified chemical or close analogues becomes available.

or

(2) 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.

13. BIBLIOGRAPHY

AGD (1998) Australian Dangerous Goods Code, Sixth Edition (ADG Code), Vol 1

FAO (Food and Agriculture Organisation of the United Nations (2000). FAO Pesticide Disposal Series 8. Assessing Soil Contamination: A Reference Manual.

IDBS (ID Business Solutions Ltd). (2002). X1fit v.3.0.5 Build 12.

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

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

SPL (2002a). AO-119-144: Determination of General Physico-chemical Properties. SPL Project Number 1078/052. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2002b) AO-119-144: Determination of Flash point. SPL Project Number 1078/061. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2002c) AO-119-144: Acute Oral Toxicity in the Rat – Acute Toxic Class Method. SPL Project Number 1078/053. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2002d) AO-119-144: Acute Dermal Irritation in the Rat. SPL Project Number 1078/055. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2002e) AO-119-144: Acute Eye Irritation in the Rabbit. SPL Project Number 1078/056. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2002f) AO-119-144: Skin Sensitisation in the Guinea Pig – Magnusson and Kligman Maximisation Method. SPL Project Number 1078/057. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2002g) AO-119-144: Reverse Mutation Assay "Ames Test" Using *Salmonella typhimurium*. SPL Project Number 1078/058. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2002h). AO-119-144 (batch AO-282-26): Assessment of Ready Biodegradability; CO_2 Evolution Test. SPL Project Number 1078/059. 22 pp. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2003a). AO-119-144: Determination of General Physico-chemical Properties. SPL Project Number 1731/010. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2003b). AO-119-144: Determination of Hazardous Physico-chemical Properties. SPL Project Number 1731/011. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2003c). AO-119-144: Assessment of the Inhibitory Effect on the Respiration of Activated Sewage Sludge. SPL Project Number 1731/018. 25 pp. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2004a). AO-119-144 (batch AO-282-26): Acute Dermal Toxicity (Limit Test) in the Rat. SPL Project Number 1731/012. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2004b). AO-119-144: Ninety Day Repeated Dose Oral (Gavage) Toxicity Study in the Rat. SPL Project Number 1731/013. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2004c). AO-119-144 (batch AO-282-26): Chromosome Aberration Test in Human Lymphocytes *In vitro*. SPL Project Number 1731/012. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2004d). AO-119-144 (batch AO-267-107): Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*). SPL Project Number 1731/015. 38 pp. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2004e). AO-119-144 (batch AO-267-107): Acute Toxicity to *Daphnia magna*. SPL Project Number 1731/016. 32 pp. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

SPL (2004f). AO-119-144 (batch AO-267-107): Algal Inhibition Test. SPL Project Number 1731/017. 35 pp. Safepharm Laboratories Ltd, P.O. Box 45, Derby, DE1 2BT, U.K.

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.