File No: STD/1168

September 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Exolit OP 1312

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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
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd, ABN: 30 069 435 552
675 Warrigal Road
Chadstone, Vic 3148

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
Other Names
CAS No.
Molecular and Structural Formula
Molecular Weight
Spectral Data
Purity
Non-Hazardous Impurities
Hazardous Imputities
Use Details
Import Volume
Identity of Manufacturing Site

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

Adsorption/ desorption
Acute inhalation toxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Not applicable

NOTIFICATION IN OTHER COUNTRIES
Korean Inventory
USA
Japan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Exolit OP 1312 (contains the notified chemical at > 60%).

3. COMPOSITION

DEGREE OF PURITY
High

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

One non-hazardous impurity at < 5%.

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is to be imported as a component of the flame retardant product Exolit OP 1312. The manufacture of the notified chemical and its formulation into Exolit OP 1312 will not occur in Australia.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1000	<1000	<1000	<1000	<1000

USE
Flame retardant for plastic material for the manufacture of electrical components and furniture.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney or Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
Clariant (Australia) Pty Ltd
675 Warrigal Road
Chadstone Vic 3148

TRANSPORTATION AND PACKAGING
Exolit OP 1312 will be imported in 25 kg cardboard boxes with polyethylene liners and transported by road to the warehouses for storage until required or directly to the end-user.

The notified chemical is not classified as a dangerous good. However, the imported product Exolit OP 1312 is classified as a dangerous good (Class 9, Environmentally hazardous substance, solid).

5.2. Operation description

Batching and Extruding
The bags (25 kg) of powdered product containing the notified chemical will be transported as required from the warehouse to the production area by forklift or manually. At the plant the powder containing the notified chemical is either weighed or added to a "loss-in weight" feeder by manually cutting open the bags or by manually scooping or pouring the powder into an enclosed and automated batching machine. An enclosed suction system may also be used to transfer powder to a drying unit and then automatically to the "loss-in weight" batch feeder. This involves inserting a large transfer tube into the bag of product containing the notified chemical. The powder is subsequently automatically suctioned to a hopper for blending with other additives. The resultant formulation is transferred automatically to a master batch extruder which is heated to the melting point of the components, and produces pelletised plastic containing 10 – < 30% of the notified chemical. The pellets are automatically packaged into 25 kg plastic bags or 500 kg bulk bags or boxes.

Moulding
The 25 kg bags or 500 kg bulk bags or boxes of reformulated pellets containing the notified chemical

(at 10 – < 30%) will be transported as required from the warehouse to the moulding plants. At the plant the pellets containing the notified chemical is either weighed or added to a "loss-in weight" feeder by manually cutting open the bags or by manually scooping or pouring into a hopper. Material from the hopper is automatically fed into the heated injection unit. The injection unit moulds the article into the desired shape. As soon as the plastic cools to a solid state, the mould opens and the finished solid plastic article is ejected from the press. The moulded plastic article can be moved manually or may be an automated production line. Purged plastic material is recycled.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport	unknown	unknown	<100 days/year
Warehouse and Storage personnel	8	1 hour per day	100 days per year
Production operators (Weighing, loading, packing pellets and cleaning)	20	4 hours per day	100 days per year
Production supervisors (Weighing, loading, packing pellets and cleaning)	4	4 hours per day	100 days per year
Quality control personnel	4	4 hours per day	100 days per year

Exposure Details

Transport and warehousing

Transport, warehouse and stores personnel will wear protective equipment (overalls/ industrial clothing and gloves as appropriate) when receiving and handling consignments of the imported product containing the notified chemical (up to 100% notified chemical). The product will be handled in the warehouse by forklift handling of pallets or manual handling of individual packages. During transport and warehousing, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

Batching and Extruding

The main routes of exposure to the notified chemical (up to 100% notified chemical) are dermal and accidental ocular and inhalation exposure during weighing and adding the imported powdered product to the automated batching and pellet-extruding machine.

Plant operators are involved in opening the imported packages containing the notified chemical and operating the suction hose which transfers the powder into the fully automated and enclosed batching machine which formulates and extrudes pellets (containing <30% notified chemical). It is possible that dermal, inhalation and accidental ocular exposure to the notified chemical by means of spillages may occur during transfer operations.

It is possible that dermal and accidental ocular and inhalation exposure may occur if manual intervention is required during the automated transfer/suction operations. It is possible that dermal exposure to pellets containing the notified chemical may occur if manual intervention is required during the automated packaging operation or the pellet packages are accidentally breached. Production operators and supervisors will have intermittent dermal exposure to the notified chemical when cleaning the equipment in general. Quality control personnel will have intermittent dermal exposure when sampling batches of the extruded pellets containing the notified chemical.

All workers involved in handling the imported product and extruded pellets will wear personal protective equipment (PPE) such as safety glasses, gloves, protective clothing and dust masks, if necessary. The batching and extruding operations occur under local exhaust ventilation (LVE). All production operators and supervisors are trained in the appropriate operational procedures and precautions.

Moulding

The main routes of exposure to the product containing the notified chemical (<30%) are dermal and accidental ocular and inhalation exposure during weighing and adding the reformulated pelleted product to the hopper. Workers may also be exposed when handling finished moulded articles.

Disposal
Workers may be involved in disposal of waste pelletised plastic or moulded plastic products.

5.4. Release

RELEASE OF CHEMICAL AT SITE
There will be no release in Australia due to manufacture as the notified chemical will not be manufactured here.

Release to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks of the polyethylene bag container. This is expected to be minor due to the packaging of the material.

RELEASE OF CHEMICAL FROM USE
There will be some residual powder left in the empty import bags. This is estimated to be less than 0.2% of the annual import volume (ie less than 2 tonnes annually). Empty bags and any residuals will be disposed of to regulated landfill.

During the extrusion process to incorporate the notified chemical into plastic grades, some waste may be generated by spillage of powder prior to incorporation into the polymer. This waste (up to 0.1% or 1 tonne of the chemical) will be collected and consigned to waste.

The process equipment will not be washed between batches. In each batch the first lot of product is discarded. This discarded material, along with any other out of specification product or off cuts will be collected and either disposed of or recycled, if possible. Any spilt material will be collected and placed into sealable containers ready for disposal.

In the end product the notified chemical is incorporated in an inert matrix and will not be released to the environment.

5.5. Disposal

All the solid wastes generated containing the notified chemical will either be disposed of to landfill. In landfill the notified chemical within the plastic matrix will not be mobile and will slowly under go abiotic and biotic degradation.

5.6. Public exposure

No manufacture of the notified chemical will take place in Australia. The chemical will only be imported as a component of Exolit OP 1312. The product will not be available for use by the general public.

This product will be used industrially for preparation of flame retardant grades of products containing the notified chemical. The industrial products will be used in production of articles in which the notified chemical is bound in the polymer system.

Plastic materials containing the notified chemical are expected to be used in the moulding of electrical components and in moulding of furniture designed for public use. The notified chemical will be bound in articles at a level of <30% based on weight of the article. Members of the public will not routinely be exposed to finished moulded articles. Electrical components will not be handled by the public. The furniture components will form part of the support structure and will not be present in normal accessible places of public contact.

The potential for exposure of the general public to Exolit OP 1312 during normal industrial storage, handling, transportation and manufacturing processes will be minimal. Only in extreme cases of inappropriate handling or accidents during transportation would there be any likelihood of the new chemical being released from the packaging and the public being exposed or contamination of the environment occurring. During normal use of plastics containing the notified chemical public exposure would be minimal.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa White, odourless powder

Melting Point/Freezing Point > 400ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Determined by differential scanning calorimetry.

In the temperature range 25–400°C no melting point of the notified chemical was observed.
TEST FACILITY HR & T Analytical Technologies (1998a)

Density 1200 kg/m^3 at 4ºC

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined by air comparison pycnometer.
TEST FACILITY HR & T Analytical Technologies (1998b)

Vapour Pressure Test not conducted.

Remarks The notified chemical is a salt and as such would be expected to have a very low vapour pressure, which is supported by DTA/TG investigations which show no weight loss even at updated temperatures.

Water Solubility < 1 mg/L at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Determined by visual estimate using the shake flask method. At the above level there was still undissolved material present. The notified chemical is very slightly soluble (Mensink *et al.* 1995)
TEST FACILITY HR & T Analytical Technologies (1998c)

Hydrolysis as a Function of pH Not possible to determine.

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.
Remarks Determination of the rate of hydrolysis was not possible due to the insolubility of the notified chemical in water, organic solvents and buffers. However, the ready biodegradability study reports complete hydrolysis occurred in a stability test within 24 h at pH 4.5. The process that occurred in the stability test is actually dissociation.
TEST FACILITY HR & T Analytical Technologies (1998d)

Partition Coefficient (n-octanol/water) Not possible to determine.

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Due to the insolubility of the notified chemical in water, organic solvents (solubility in octanol <15.4 mg/L) and buffers neither the HPLC Method or Flask Method could be used to determine the partition coefficient.
TEST FACILITY HR & T Analytical Technologies (1998e)

Adsorption/Desorption Not determined

Remarks The low water solubility of the notified chemical indicates it would partition to soil and sediment.

Particle Size 2 – 40 µm (D_{50})

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm)	*Mass (%)*
<3	10
3-6	20
7-10	10
11-21	30
22-34	20
35-88	10

Remarks Respirable fraction 40% < 10 μm
Inhalable fraction 60% < 100 μm
TEST FACILITY Clariant (1998)

Flash Point Not determined.

Remarks Test not conducted because the notified chemical is a solid.

Flammability Limits The notified chemical could not be ignited with a flame.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks None.
TEST FACILITY HR & T Analytical Technologies (1998f)

Autoignition Temperature No self-ignition was noted up to a temperature of 402ºC.

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks None.
TEST FACILITY HR & T Analytical Technologies (1998g)

Explosive Properties As no exothermic effect occurred up to 400ºC it was concluded no hazard or explosive properties exists for the notified chemical.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks A negative result is predicted on structural grounds.
TEST FACILITY HR & T Analytical Technologies (1998h)

Reactivity Not expected to be reactive under normal environmental conditions.

Dust Explosivity The product may cause dust explosions, lowest ignition energy 13 mJ

METHOD Unknown
Remarks Statement from manufacturer, Clariant GmbH. No report available.
TEST FACILITY Unknown

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
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 1000 mg/kg bw
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations in Chinese Hamster V79 cells	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 401 Acute Oral Toxicity.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).

Species/Strain	Rat/HSD: Sprague Dawley
Vehicle	Sesame oil DAB 10 (20% suspension)
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	2000	0/5
2	5 females	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity	None.
Effects in Organs	No adverse macroscopic observations at necropsy.
Remarks - Results	There were no deaths or notified chemical related clinical signs or remarkable body weight changes during the study period.

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

TEST FACILITY — Hoechst Marion Roussell (1998a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE — Notified chemical.

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

Species/Strain	Rat/ HSD:Sprague Dawley SD
Vehicle	Sesame oil (Oil sesami DAB 10)
Type of dressing	Occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5	2000	0/5
2	5	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were no notified chemical-related dermal reactions.
Signs of Toxicity - Systemic	There were no notified chemical-related dermal reactions.
Effects in Organs	No abnormalities were observed upon macroscopic examination at the end of the study.
Remarks - Results	There were no deaths or notified chemical related clinical signs or remarkable body weight changes during the study period. The skin of the animals showed no signs of irritation.

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

TEST FACILITY Hoechst Marion Roussell (1998b)

7.3. Acute toxicity – inhalation

Remarks Test not conducted

7.4. Irritation – skin
7.4.1 Study 1

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 albino White
Number of Animals	3
Vehicle	Polyethylene glycol
Observation Period	72 h
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	0	0	0	-	0
Oedema	0	0	0		-	0

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

Remarks - Results There were no deaths or test substance related clinical signs or remarkable body weight changes during the study period. There were no dermal reactions.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY Hoechst Marion Roussell (1997a)

7.4.2 Study 2

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
US EPA OPPTS 870.2500, Health Effects Test Guidelines: Acute Dermal Irritation.

Species/Strain	Rabbit/New Zealand albino White
Number of Animals	3
Vehicle	Deionised water.
Observation Period	72 h

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	0	0	0	-	0
Oedema	0	0	0		-	0

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

Remarks - Results None.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY Aventis Pharma (2003a)

7.5. Irritation – eye
7.5.1 Study 1

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 h
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	1.3	1.0	1.0	3	2 days	0
Conjunctiva: chemosis	0.3	0.3	0.3	2	1 day	0
Conjunctiva: discharge	0.3	0	0.3	1	1 day	0
Corneal opacity	0.3	0	0	1	1 day	0
Iridial inflammation	0.3	0	0	1	1 day	0

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

Remarks - Results One hour up to two days after administration the conjunctivae of the animals showed injected blood vessels up to a deeper crimson red colour. One hour up to one day after administration slight swelling up to obvious swelling were observed. One day after administration the cornea of one animal showed scattered or diffuse areas of opacity and the iris was reddened. Additionally, clear-colourless eye discharge occurred one hour after administration. Three days after administration all signs of irritation were reversed.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Hoechst Marion Roussell (1997b)

7.5.2 Study 2

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

	EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation). US EPA OPPTS 870.2400 Health Effects Test Guidelines: Acute Eye Irritation.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 h
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	0.3	0	0	2	1 day	0
Conjunctiva: chemosis	0.3	0	0	1	1 day	0
Conjunctiva: discharge	0	0	0	1	1 hour	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	None.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Aventis Pharma (2003b)

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 406 Skin Sensitisation - Magnusson and Kligman. EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson and Kligman.
Species/Strain	Guinea pig/Pirbright-White females
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: Freund's Complete Adjuvant by itself caused severe irritation topical: 25% (w/v)
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 5% (w/v in sesame oil (Oleum sesami DAB 10) topical: 25% (w/v) in sesame oil (Oleum sesami DAB 10)
Signs of Irritation	Intradermal injection: The intradermal injections with Freund's Complete Adjuvant (with and without notified chemical) caused severe erythema and oedema as well as indurations and encrustations. The administration sites treated with notified chemical in Oleum sesami DAB 10 showed slight erythema and oedema. Intradermal injections of the vehicle alone exhibited no signs of irritation. Topical Induction: After removal of the patches at Day 10, severe erythema and oedema, indurated, scabbed and encrusted skin as well as necrosis was observed at the sites previously treated with Freund's Complete Adjuvant. The administration of the notified chemical or vehicle alone exhibited no signs of irritation.
CHALLENGE PHASE	
1st challenge	topical: 25% (w/v)
Remarks - Method	No significant protocol deviations.
RESULTS	No dermal reactions were seen in either the control or the test groups at

	24 or 48 hours after patch removal.
Remarks - Results	None.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Hoechst Marion Roussell (1998c)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical.
Method	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC DIRECTIVE 96/54/EC B.7 REPEATED DOSE (28 DAYS) TOXICITY (ORAL).
Species/Strain	Rat/Wistar
Route of Administration	Oral - gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week.
Vehicle	Deionised water.
Remarks – Method	No protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	"	62.5	1/10
III (mid dose)	"	250	0/10
IV (high dose)	"	1000	0/10

Mortality and Time to Death

One female of the low dose group died on day 3 from a technical error.

Clinical Observations

High dose males exhibited pultaceous faeces on day 24. Body weights and body weight gain were unaffected by treatment.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

High dose females exhibited a decreased mean cell volume but other red blood cell parameters were unaffected. High dose females also exhibited increased leukocyte count but it was within the normal physiological range. High dose males exhibited increased chloride and high dose females exhibited increased sodium, and decreased glucose and alanine aminotransferase. All clinical chemistry observations were within the normal physiological range. No treatment-related urinalysis changes were noted.

Effects in Organs

High dose males exhibited increased relative liver weights and high dose females increased relative adrenal weights but the changes were within the normal physiological range. No macroscopic or microscopic effects were observed.

Remarks – Results

None.

CONCLUSION

In conclusion, the notified chemical caused no adverse effects when administered 28 times during 29 days at the dose level of 1000 mg/kg body weight per day. The death of 1 female animal of the low dose group on day 3 of the study was due to technical error. The occurrence of pultaceous faeces in male animals of the high dose group on day 24 of the study is not considered to be of toxicological relevance.

The "No Observed Adverse Effect Level" (NOAEL) is 1000 mg/kg body weight per day based on no adverse effects occurring at this dose level and the NOEL is 250 mg/kg bw/day.

TEST FACILITY Hoechst Marion Roussell (1998d)

7.8. 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, TA100, TA98
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 4–5000 µg/plate b) Without metabolic activation: 4–5000 µg/plate
Vehicle	Dimethyl Sulfoxide
Remarks - Method	Visible precipitation of the notified chemical was observed at 500 µg/plate and above.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	No toxicity observed	No toxicity observed	500, 2500, 5000	None
Test 2	No toxicity observed	No toxicity observed	500, 2500, 5000	None
Present				
Test 1	No toxicity observed	No toxicity observed	500, 2500, 5000	None
Test 2	No toxicity observed	No toxicity observed	500, 2500, 5000	None

Remarks - Results Concurrent positive controls demonstrated the sensitivity of the assay and the metabolising activity of the liver preparations. Negative controls were within historical limits.

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

TEST FACILITY Hoechst Marion Roussell (1998e)

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	Chinese Hamster lung fibroblasts Cell line V79
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction.
Vehicle	Suspended in Na_2HPO_4 (0.2 M) and NaH_2PO_4 (0.2 M)
Remarks - Method	None.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1.0, 7.8*, 10, 25*, 50, 78*, 100, 250, 500, 700	3 h	20
Test 2	1.0, 7.8*, 10, 25*, 50, 78*, 100, 250, 500, 700	3 h	20
Present			

Test 1 Test 2	1.0, 7.8*, 10, 25*, 50, 78*, 100, 250, 500, 700	20 h	20

*Cultures selected for metaphase analysis.

RESULTS

Evaluation of higher dose levels (250 and 780 µg/mL) was not possible because of heavy precipitation of the test compound on the slides.

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None	None	None	None
Test 2	250, 500, 780	None	250, 500, 780	None
Present				
Test 1	None	None	None	None
Test 2	None	None	None	

Remarks - Results

Cytotoxicity was not observed at any test concentration. No statistically or biologically significant increases in the percentage of aberrant cells above the vehicle control levels, were recorded for any cultures treated with the notified chemical in either the presence or absence of metabolic activation. Positive controls confirmed the sensitivity of the test system.

CONCLUSION

The notified chemical was not clastogenic to Chinese Hamster V79 cells treated in vitro under the conditions of the test.

TEST FACILITY

Hoechst Marion Roussell (1998f)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified substance
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I). Method of testing the biodegradability of chemical substances by micro-organisms, in Testing methods for new chemicals substances, July 13, 1974, No 5 Planning and Coordination Bureau, Environment Agency.
Inoculum	Activated sludge – city plant
Exposure Period	28 days
Auxiliary Solvent	
Analytical Monitoring	BOD by Closed system oxygen consumption measurement – soda lime. TOC/DOC
Remarks - Method	Reference substance – aniline Concentration of suspended solids – 30 mg/L Treatments: - water + test substance – 100 mg/L – vessel 1 - sludge + test substance – 100 mg/L – vessel 2, 3 and 4 - sludge + aniline – 100 mg/L – vessel 5 - control blank – activated sludge only – vessel 6 Temperature measured daily – 25^{o}C BOD was measured by data sampler and autorecorder. At termination of study the dissolved organic carbon, test substance concentration and pH were measured.

RESULTS

Percentage biodegradation – ONLY in test solutions (Vessels 2, 3 & 4)

Method	% degradation			
	Vessel 2	Vessel 3	Vessel 4	Average
BOD	0	0	0	0
TOC	0	2	0	1

Remarks - Results	The reference substance (aniline) degraded by 75.3% after 28 d confirming the suitability of the inoculum and test conditions.. Solutions were not analysed for the test substance due to the rapid dissociation of the test material. Analysis for the dissociation products resulted in recoveries of between 94 and 101%.
CONCLUSION	Under the study conditions the test substance was not readily biodegradable.
TEST FACILITY	Kurume (2004)

8.1.2. Bioaccumulation

Not determined. The notified chemical rapidly dissociates in water and will not bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemcial
METHOD	OECD TG 203 Fish, Acute Toxicity Test -Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish –Static.
Species	Zebra fish (*Danio rerio*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	2.1-2.5 mmol Ca^{2+} + Mg^{2+}/L
Analytical Monitoring	HPLC with UV detection
Remarks – Method	Based on range-finding tests it was determined that a limit test at 100 mg/L would be done. A measured amount of test substance was homogenized in water by ultrasonication and added to the test chamber without filtration and stirred for 24 h prior to the addition of fish. The concentration and stability of the test solution was determined at 0, 48 and 96 hours. The test solutions showed a light turbidity. Particulate matter was observed on the water surface and the bottom of the vessel. The test vessels, each with 10 fish, were covered, maintained between 21-22°C, exposed to a photoperiod of 16 dark/8 hours light and were aerated throughout the study. Temperature (21.1-21.8°C for test vessel and 21.3-21.6°C for control), pH (7.5-7.7 test vessel and 7.5-8.1 control) and dissolved oxygen (6.7-9.0 mg/L test solution and 6.9-10.3 mg/L control) were recorded daily. Observations were made at 3, 6, 24, 48, 72 and 96 hours with the fish being transferred to clean water for the observations.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual**		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	-	7	0	0	0	0	0
100	11.0	7	0	0	0	0	0

*Mean concentration the initial measured concentration 18.7 mg/L, 48 h measured concentration of 7.6 mg/L and 96 h concentration of 6.8 mg/L.

LC50	>100 mg/L at 96 hours. (nominal).
LOEC	100 mg/L at 96 hours. (nominal).
Remarks – Results	From the analytical method it is unclear whether the concentrations being measured were for the test substance or a dissociation product (noting that the solutions were stirred for 24 h prior to the addition of test organisms and that a stability test reported in the biodegradation study observed 100% dissociation of the notified chemical within 24 h). The fish showed changes in behaviour, swimming behaviour and respiration rate in all tested concentration groups at all times.
CONCLUSION	The notified chemical has an LC50 greater than its solubility at > 100 mg/L (nominal concentration). However, some sub-acute effects were observed.
TEST FACILITY	Hoechst Marion Roussell (1998g)

8.2.2.a Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.
Species	*Daphnia magna*

Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not specified.
Analytical Monitoring	HPLC UV detection
Remarks - Method	Based on range-finding tests it was determined that a limit test at 100 mg/L would be done. A measured amount of test substance was homogenized in water by ultrasonication and added to the test chamber without filtration and stirred for 24 h prior to the addition of daphnia. The concentration and stability of the test solution was determined at 0 and 48 h. The test solutions showed a light turbidity. Particulate matter was observed on the water surface. The test vessels (2 replicates), each with 10 daphnia, were covered, maintained at 21ºC, exposed to a photoperiod of 16 dark/8 hours light and were not aerated throughout the study. Temperature (21.2-21.4°C for test vessel and 20.1-21.1°C for control) was recorded daily, while pH (7.3-7.6 for test vessel and 8.2-8.3 for control) and dissolved oxygen (8.4-8.6 mg/L for test vessel and 8.7-9.0 for control) were recorded at the start and end of the study. Observations were made at 24 and 48 hours. Two controls were done in parallel.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20		
100	33.7*	20		

*Mean concentration the initial measured concentration 66.01 mg/L and 48 h measured concentration of 1.31 mg/L..

LC50	>100 mg/L at 48 hours (nominal).
NOEC	100 mg/L at 48 hours (nominal).
Remarks - Results	From the analytical method it is unclear whether the concentrations being measured were for the test substance or a dissociation product (noting that the solutions were stirred for 24 h prior to the addition of test organisms and that a stability test reported in the biodegradation observed 100% dissociation of the notified chemical within 24 h). No immobility was observed up to the limit of the solubility.

CONCLUSION The test material is not toxic to daphnia up to the limit of its solubility.

TEST FACILITY Hoechst Marion Roussell (1998h)

8.2.2.b Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical.

METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – semi static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Semi-static.
Species	*Daphnia magna*
Exposure Period	21 days
Auxiliary Solvent	None
Water Hardness	2.1-2.7 mmol Ca^{2+} + Mg^{2+}/L (test vessel) 2.1-2.5 mmol Ca^{2+} + Mg^{2+}/L (control vessel)
Analytical Monitoring	HPLC refractive index detection
Remarks - Method	Test concentrations were prepared by adding a weighed amount of test substance into a beaker, mixed with test medium and ultrasonicated for 10 min. Mixtures were then stirred for 24 h prior to adjusting the pH to 7.0-7.2 and passed through a 0.2 µm filter. Test media were refreshed

every Monday, Wednesday and Friday during the study. All test solutions were observed to be clear. All environmental parameters (pH, Dissolved O_2 and temperature) were within acceptable ranges.

The EC50, NOEC and LOEC values were determined if possible, for the parameters mobility and reproductive output (as mean cumulative offspring) using he statistical software ToxRat Professional 2.09. The method of analysis is uncertain.

RESULTS

Concentration mg/L		Number of D. magna	*Number Immobilised*					
Nominal	*Actual*	10	*1 d*	*2 d*	*4 d*	*14 d*	*15 d*	*21 d*
0	-	10	0	0	0	0	0	0
1	1.014	10	0	0	0	0	0	0
3.2	3.250	10	0	0	0	0	0	0
10	10.049	10	0	0	0	0	0	0
32	31.907	10	0	0	0	2	7	8
100	98.410	10	0	5	10	10	10	10

LC50	22.3 (CI 16.3-30.6) mg/L at 21 days immobility (immobility of parent) 46.2 (CI 44.5-48.1) mg/L at 21 days reproduction
NOEC	10 mg/L at 21 days (immobility of parent) 10 mg/L at 21 days (reproduction)
LOEC	32 mg/L at 21 days (immobility of parent) 32 mg/L at 21 days (reproduction)
Remarks - Results	From the analytical method it is unclear whether the concentrations being measured were for the test substance or a dissociation product (noting that the solutions were stirred for 24 h prior to the addition of test organisms and that a stability test reported in the biodegradation observed 100% dissociation of the notified chemical within 24 h). The latter seems highly likely particularly as the analytical method used is not specific for the test material and would explain the apparently high water solubility in this study. In the control group, no mortality occurred and the mean number of living offspring produced per parent animal was 80.1, thus fulfilling the validity criteria for the test. All test animals in the highest test concentration died within 4 days of exposure. At 32 mg/L test level mortality 80% mortality was observed at the end of the study with mortalities first noted at 14 days. No mortalities occurred in the three lower test concentration. Surviving animals of all concentration groups showed no difference in the onset of brood production in comparison to the control and the reproduction rate in the three lowest test concentrations were not statistically different from the control.
CONCLUSION	The test material is very slightly toxic to daphnia under the study conditions (Mensink *et al.* 1995).
TEST FACILITY	Safety Science and Quality Services (2005)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified substance
METHOD	EC Directive 92/69/EEC No. L383 C.3 Algal Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 3.2, 5.8, 10, 18, 32, 58, 100, 180 mg/L Measured* 2.2, 6.4, 11.1, 18.9, 29, 54, 88, 153 mg/L

*Measured as Al^{3+} through complexation with Alizarinred.

Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	Spectrophotometry
Remarks - Method	A 360 mg/L stock solution was prepared. Dispersion of the test material was achieved by ultrasonication for 45 min at 40°C and stirring. Test concentrations were prepared by dilution from the stock solution. An initial cell density of 1×10^4 cells/mL was used. Constant illumination and stirring, and temperature maintained at between 22.1-236.78.1°C. The addition of the test material to the test media resulted in a pH effect as shown below

Test Substance Concentration mg/L		pH	
Nominal	Actual	Initial	72 h
control		7.92	8.47
3.2	2.2	7.83	8.35
5.8	6.4	7.74	8.22
10	11.1	7.65	8.09
18	18.9	7.47	8.00
32	29	7.31	7.91
58	54	7.02	7.76
100	88	5.92	6.78
180	153	4.44	4.70
180 (pH control)	164	7.98	7.05

RESULTS

Biomass		*Growth*	
E_bC50	*NOE_bC*	*E_rC50*	*NOE_rC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
60 (54.7-65.2)	2.2	76 (68.5 – 83.6)	2.2

Remarks - Results	The solubility of the test substance in the test medium was checked. After 72 h the test substance had completely sedimented. In the pH control the pH was adjusted and no inhibition of growth was observed compared to the control.
CONCLUSION	Under the study conditions, the test substance is harmful to algae (United Nations 2003).
TEST FACILITY	Dr U Noack-Laboratorium (1998a)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sewage sludge from a domestic STP
Exposure Period	3 hours
Concentration Range	Nominal: 320, 580, 1000, 1800, 3200, 5800, 10000 mg/L
Remarks – Method	The study was conducted as a single test vessel per concentration and duplicate controls. Vessels were aerated during the tests, and O_2 consumption rates were monitored. Temperature was maintained at 21°C. Duplicate controls were run in parallel.

	Reference substance – Copper(II) sulphate pentahydrate Rate of respiration was determined after 3 hours contact. Total water hardness – 100 mg/L $CaCO_3$.
RESULTS	
EC50	1968 (CI 1629-2376) mg/L
NOEC	483 mg/L
Remarks – Results	Reference substance 3 h EC_{50} = 100 mg/L The validity criteria for control respiration rates variation and reference material toxicity were satisfied. Environmental parameters were within acceptable ranges.
CONCLUSION	Under the study conditions the test substance is not toxic to micro-organisms.
TEST FACILITY	Dr U Noack-Laboratorium (1998b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The proposed use and disposal pattern for the notified chemical suggests that direct release to the aquatic and terrestrial environmental compartments of the environment is unlikely and therefore no predicted environmental concentration (PEC) has been estimated for the notified chemical.

Wastes containing the notified chemical generated during pellet formulation and end-product moulding are expected to be disposed of to landfill or incinerated. Up to 165 kg per annum of the notified chemical could be disposed of to landfill, including as residues in empty containers. Most of this waste would be cured product in which case the chemical will be incorporated into an inert matrix and will be unavailable to the environment. It is unlikely that the notified chemical will leach into the water compartment due to its low solubility.

Should blooming of the notified chemical occur in the polymers that it has been incorporated in, the chemical will slowly make its way to the surface where it will not be volatile. In the event that these surfaces come into contact with water the chemical will dissolve, through dissociation, and be washed off the surface. This will occur in a very disperse manner.

At the end of their useful lives articles made containing the notified chemical would be disposed of to landfill or recycled.

The notified chemical rapidly dissociates in water and will not bioaccumulate.

9.1.2. Environment – effects assessment

The aquatic toxicity data submitted for the 4 taxa (fish, invertebrates, algae and micro-organisms) indicates that the chemical is slightly toxic to aquatic invertebrates and algae and slightly toxic to fish. The most sensitive species was algae with a reported NOEC of 2.2 mg/L at 72 hours. A predicted no effect concentration for aquatic organisms ($PNEC_{aquatic}$) of 44 µg/L has been derived by dividing this by a safety factor of 50 as chronic data is available.

9.1.3. Environment – risk characterisation

The notified chemical does not pose a significant risk to the environment based on its reported use pattern because there will be very low environmental exposure. The majority of the chemical will be contained in a cured polymeric matrix. The majority of the notified chemical will eventually be disposed of to landfill in the final products at the end of their useful lives.

Despite the low PNEC, it is appreciated that there is unlikely to be any release of the chemical into the aquatic environment under the proposed use patterns. Given the low aquatic exposure a meaningful PEC can not be calculated and levels are expected to be well below the safety margin.

Tests show that the notified chemical has a low potential to bioaccumulate and that it is not readily biodegradable. However, abiotic or slow biotic processes are expected to be largely responsible for the eventual degradation of the notified chemical.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical is imported as a fine powder in 25 kg lined cardboard boxes. Transport or warehouse workers can be exposed in the event of accidental breach of the containers.

The main operation during which inhalation exposure could occur will be after slitting the inner polyethylene bag and scooping or suctioning the powder to the mixing vessel. This exposure is controlled by the use of LEV and dust masks if required. Some dermal or ocular exposure can occur and will be controlled by the use of impervious gloves and safety goggles. Once the

powder has been added to the mixing vessel, it is in a closed system and exposure should be precluded. In addition, the notified chemical is encapsulated within a matrix and should not be bioavailable. Therefore, exposure during subsequent moulding operations should also be precluded.

9.2.2. Public health – exposure assessment

Under normal circumstances the public should potentially only contact the notified chemical when it is incorporated in a solid matrix. However, the electrical components and furniture components are not likely to be contacted by the public and public exposure would therefore be restricted to release of the chemical after a transport accident.

9.2.3. Human health – effects assessment

The notified chemical was of low acute oral and dermal toxicity in rats, was not a skin irritant and was a slight eye irritant in rabbits and was not a skin sensitiser in guinea pigs. No systemic toxicity was identified in a 28-day repeated oral toxicity study and the notified chemical was neither mutagenic in bacteria nor clastogenic in Chinese Hamster V79 cells in vitro.

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

Given the limited opportunity for exposure (limited to transfers of the imported notified chemical in powder form to the mixing vessel in which the plastic is formed) and the low hazard indicated by a complete data set for this standard notification, there is virtually no risk of adverse health effects to workers involved in plastic manufacture and moulding operations. There is a low probability that nuisance dust levels could exceed the NOHSC exposure standard of 10 mg/m^3 (NOHSC, 1995) and this would be unlikely to occur. The main risk to workers will be contact with hot plastic and this can be expected on an intermittent basis.

9.2.5. Public health – risk characterisation

As the notified chemical is of low hazard and exposure of the public is unlikely, the risk to the public from importation of the notified chemical and use and disposal in the manner described is considered to be negligible.

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*.

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 described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product to be imported containing 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 product to be imported containing 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

- The following control measures should be implemented by plastic manufactures to minimise environmental exposure during use of the notified chemical:
  - Ensure all process areas are bunded with all drains going to collection pits or on-site treatment plants.

Disposal

- The notified chemical should be disposed of by recycling, landfill or incineration

Emergency procedures

- Spills/release of the notified chemical should be handled by containment, collection and storeage in a sealable labelled container ready for disposal.

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(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

Aventis Pharma (2003a) Rabbit Skin Irritation [NOTIFIED CHEMICAL]: Study Number PT02-0385, Aventis Pharma Deustchland GmbH, Testing Facility Kastengrund, ProTox, Mainzer Landstr. 500, D-65795 Hattersheim, GERMANY (unpublished report provided by the notifier).

Aventis Pharma (2003b) Rabbit Eye Irritation [NOTIFIED CHEMICAL]: Study Number PT02-0386, Aventis Pharma Deustchland GmbH, Testing Facility Kastengrund, ProTox, Mainzer Landstr. 500, D-65795 Hattersheim, GERMANY (unpublished report provided by the notifier).

Clariant GmbH (1998) Particle Size [NOTIFIED CHEMICAL]: Study Number Ol-104 (Confirm), Clariant GmbH, BU AD, Knapsack, GERMANY (unpublished report provided by the notifier).

Dr U Noack Laboratorium (1998a) [NOTIFIED CHEMICAL] Alga, Growth Inhibition test (72[h]): Tox-Bericht-Nr.: 000913. Dr U Noack Laboratorium für Angewandte Biologie, Sarstedt Germany (umpublished report supplied by notifier).

Dr U Noack Laboratorium (1998b) [NOTIFIED CHEMICAL] Respiration inhibition test with activated sludge: Tox-Bericht-Nr.: 000914. Dr U Noack Laboratorium für Angewandte Biologie, Sarstedt Germany (umpublished report supplied by notifier).

HR & T Analytical Technologies (1998a) Melting Point/Melting Range [NOTIFIED CHEMICAL]: Study Number SI003-98, Hoechst Research and Technology, Deutschland GmbH & Co. KG D-65926, Frankfurt am Main, GERMANY (unpublished report provided by the notifier).

HR & T Analytical Technologies (1998b) Relative Density [NOTIFIED CHEMICAL]: Study Number SI004-98, Hoechst Research and Technology, Deutschland GmbH & Co. KG D-65926, Frankfurt am Main, GERMANY (unpublished report provided by the notifier).

HR & T Analytical Technologies (1998c) Water Solubility [NOTIFIED CHEMICAL]: Study Number EO 002-98, Hoechst Research and Technology, Deutschland GmbH & Co. KG D-65926, Frankfurt am Main, GERMANY (unpublished report provided by the notifier).

HR & T Analytical Technologies (1998d) Abiotic Degradation, Hydrolysis as a Function of pH [NOTIFIED CHEMICAL]: Study Number EO 001-98, Hoechst Research and Technology, Deutschland GmbH & Co. KG D-65926, Frankfurt am Main, GERMANY (unpublished report provided by the notifier).

HR & T Analytical Technologies (1998e) Partition Coefficient N-Octanol/Water [NOTIFIED CHEMICAL]: Study Number EO 003-98, Hoechst Research and Technology, Deutschland GmbH & Co. KG D-65926, Frankfurt am Main, GERMANY (unpublished report provided by the notifier).

HR & T Analytical Technologies (1998g) Flammability (Solids) [NOTIFIED CHEMICAL]: Study Number SI010-98, Hoechst Research and Technology, Deutschland GmbH & Co. KG D-65926, Frankfurt am Main, GERMANY (unpublished report provided by the notifier).

HR & T Analytical Technologies (1998h) Auto-Flammability (Solids-Determination of Relative Self-ignition Temperature) [NOTIFIED CHEMICAL]: Study Number SI006-98, Hoechst Research and Technology, Deutschland GmbH & Co. KG D-65926, Frankfurt am Main, GERMANY (unpublished report provided by the notifier.)

HR & T Analytical Technologies (1998i) Expert Statement [NOTIFIED CHEMICAL]: Hoechst Research and Technology, Deutschland GmbH & Co. KG D-65926, Frankfurt am Main, GERMANY (unpublished report provided by the notifier).

Hoechst Marion Roussell (1997a) Test for Primary Dermal Irritation in the Rabbit [NOTIFIED CHEMICAL]: Study Number 97.0792, Hoechst Marion Roussell, Global Preclinical Development, Drug Safety, D-65926 Frankfurt, GERMANY (unpublished report provided by the notifier).

Hoechst Marion Roussell (1997b) Test for Primary Eye Irritation in the Rabbit [NOTIFIED CHEMICAL]: Study Number 97.0822, Hoechst Marion Roussell, Global Preclinical Development, Drug Safety, D-65926 Frankfurt, GERMANY (unpublished report provided by the notifier).

Hoechst Marion Roussell (1998a) Testing for Acute Oral Toxicity in the male and female Sprague Dawley Rat [NOTIFIED CHEMICAL]: Study Number 98.0269, Hoechst Marion Roussell, Global Preclinical Development, Drug Safety, D-65926 Frankfurt, GERMANY (unpublished report provided by the notifier).

Hoechst Marion Roussell (1998b) Testing for Acute Dermal Toxicity in the male and female Sprague Dawley Rat [NOTIFIED CHEMICAL]: Study Number 98.0246, Hoechst Marion Roussell, Global Preclinical Development, Drug Safety, D-65926 Frankfurt, GERMANY (unpublished report provided by the notifier).

Hoechst Marion Roussell (1998c) Testing for Sensitising Properties in the Pirbright-White Guinea Pig in the Maximisation Test [NOTIFIED CHEMICAL]: Study Number 97.0733, Hoechst Marion Roussell, Global Preclinical Development, Drug Safety, D-65926 Frankfurt, GERMANY (unpublished report provided by the notifier).

Hoechst Marion Roussell (1998d) [NOTIFIED CHEMICAL] Testing for Subacute Oral Toxicity (28 Applications within 29 Days) in the Male and Female Wistar Rat. Study No. 97.0736, Hoechst Marion Roussell, Global Preclinical Development, Drug Safety, D-65926 Frankfurt, GERMANY (unpublished report provided by the notifier).

Hoechst Marion Roussell (1998e) Bacterial Reverse Mutation Test [NOTIFIED CHEMICAL]: Study Number 98.0242, Hoechst Marion Roussell, Global Preclinical Development, Drug Safety, D-65926 Frankfurt, GERMANY (unpublished report provided by the notifier).

Hoechst Marion Roussell (1998f) In Vitro Mammalian Chromosome Aberration Test in V79 Chinese Hamster Cells [NOTIFIED CHEMICAL]: Study Number 98.0366, Hoechst Marion Roussell, Drug Innovation and Approval, Lead Optimization, Dept of Toxicology/Pathology, D-65926 Frankfurt am Main, GERMANY (unpublished report provided by the notifier).

Hoechst Marion Roussell (1998g) [NOTIFIED CHEMICAL] 96-hour acute toxicity study in *Daphnia magna* (water flea) Report Number 98.0123, Hoechst Marion Roussell, Global Preclinical Development, Drug Safety, D-65926 Frankfurt, GERMANY (unpublished report provided by the notifier).

Hoechst Marion Roussell (1998h) [NOTIFIED CHEMICAL] 48-hour acute toxicity study in zebra fish (*Danio rerio*): Report Number 98.0180, Hoechst Marion Roussell, Global Preclinical Development, Drug Safety, D-65926 Frankfurt, GERMANY (unpublished report provided by the notifier).

Kurume (2004) Biodegradation Study of [NOTIIFIED CHEMICAL] in Microorganisms. Study No. 14009. Kurume Laboratory, Japan (unpublished report provided by the notifier).

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 (1995) Proposed National Exposure Standards for Atmospheric Contaminants in the Occupational Environment, Australian Government Publishing Service, Canberra, 1995.

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.

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

Safety Science and Quality Services (2005) [NOTIFIED CHEMICAL] *Daphnia magna* Reproduction Test. Study No. PT04-0255. Safety Science and Quality Services, Hattersheim, GERMANY (unpublished report provided by the notifier).