File No: STD/1237

April 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

IRGAFOS 38

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 Water Resources.

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

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

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd (ABN 97 005 061 469)
235 Settlement Road
Thomastown Vic 3074

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 NUMBER
MOLECULAR FORMULA
STRUCTURAL FORMULA
SPECTRAL DATA
PURITY
IMPORT VOLUME
IDENTITY OF CUSTOMER SITES

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)
Previously notified as CEC/649.

NOTIFICATION IN OTHER COUNTRIES
EU (ELINCS) – (1994)
USA (TSCA) – (1996)
Canada (NDSL) – (2004)
China (IECSC) – (2003)
Japan (ENCS) – (2002)
Korea (KECI) – (2002)
Philippines (PICCS) – (not known)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
CG 30-1389
TKA 40016

MARKETING NAME(S)
IRGAFOS® 38

ANALYTICAL DATA
Reference NMR, IR, GC, and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa White crystals with no odour

Property	Value	Data Source/Justification
Melting Point/Freezing Point	90.0°C	Measured
Boiling Point	> 358°C at 101.3 kPa	Measured
Density	1050 kg/m^3 at 23ºC	Measured
Vapour Pressure	9 x 10^{-6} Pa at 25ºC	Extrapolated from measured data
Water Solubility	< 2 x 10^{-5} g/L at 20ºC	Measured
Hydrolysis as a Function of pH	Not determined	Water solubility is below the detection limit of available analytical methods.
Partition Coefficient (n-octanol/water)	log Pow at 20ºC = ≥ 12	Calculated
Adsorption/Desorption	log K_{oc} = » 5.6 at 20°C.	Estimated
Dissociation Constant	Not determined	No dissociation constant in an accessible pH range.
Particle Size	Inhalable fraction (<100 µm): 18% Respirable fraction (<10 µm): <2% MMD = 186 µm	Measured
Flash Point	Not determined	Notified chemical is a low-volatility solid.
Flammability Limits	Not considered highly flammable	Measured
Autoignition Temperature	No self-ignition detected	Measured
Explosive Properties	Not considered explosive	Measured
Oxidising Properties	Not considered an oxidizing substance	Measured

Discussion of Observed Effects

For full details of the physical-chemical properties tests please refer to Appendix A.

Reactivity

The notified chemical is stable under normal conditions of use. Based on the MSDS for IRGAFOS 38, strong acids, strong bases and strong oxidising agents have been identified as incompatible materials. Static discharges should also be avoided. The decomposition temperature has been determined to be greater than 358°C and typical decomposition products include oxides of carbon, oxides of phosphorus and other toxic gases/vapours (not identified).

Dangerous Goods classification

Based on the available physico-chemical properties the notified chemical is not classified as a Dangerous Good according to the Australian Dangerous Goods Code (FORS, 1998).

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical, marketed as IRGAFOS 38, is not manufactured in Australia but will be imported from Europe by sea.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1 – 10	1 – 10	1 – 10	1 – 10	1 – 10

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Ciba Specialty Chemicals Pty Ltd (Thomastown, Victoria) and customers in Victoria.

TRANSPORTATION AND PACKAGING
IRGAFOS® 38 is transported into Australia by ship in 40-kg robust UN approved (4G) plastic-lined fibreboard cartons. The product is transported from the dockside to the Ciba Specialty Chemicals warehouse in Thomastown, where it is stored until required for despatch to customers. The finished polyolefins, polyolefin copolymers and coating resins will be packaged in 20 kg or 25 kg plastic bags or 20 kg or 25 kg sealed fibreboard cartons. The finished products will be distributed to numerous premises around Australia.

The imported product is stored within the warehouse on sturdy racking until required for despatch to customer sites. The product is not classified as a dangerous good for transport, so there are no special storage or transport requirements.

USE
Processing stabiliser for coating resins (powder coatings), polyolefins and olefin copolymers.

The product protects polymers from thermo-oxidative degradation during processing, working against discoloration of the polymer.

OPERATION DESCRIPTION

Formulation and Article Production – Polyolefins and Olefins Copolymers
At the customer sites, the notified chemical will be either blended with other additives and extruded directly into end use articles (containing 0.1-0.2% notified chemical) or blended and extruded to produce intermediate masterbatch pellets, which will be sold to customers for later extrusion.

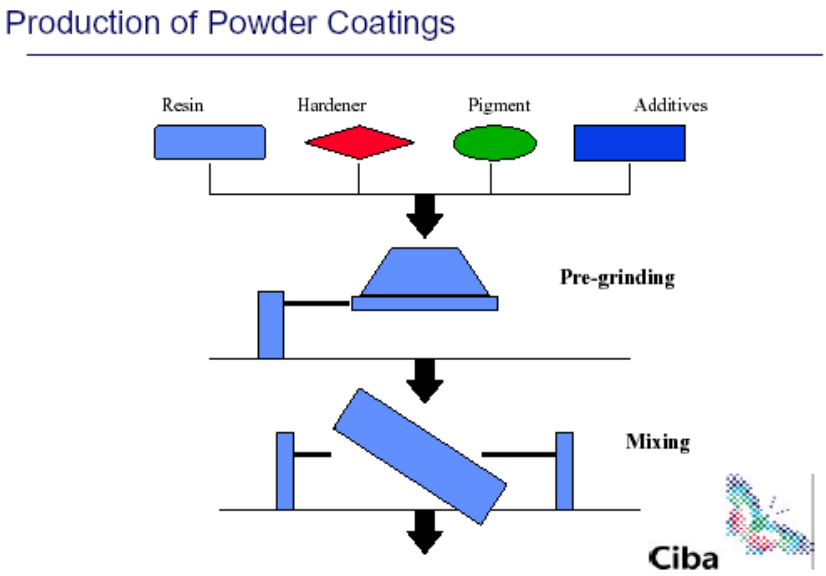
Extrusion plant operators will pour granules containing the notified chemical (either the imported product or formulated masterbatch pellets) manually into the hopper of the extruder. Prior to use, laboratory technicians will also manually scoop a required amount of product for quality analysis sampling. Engineering controls, such as local exhaust ventilation, are expected to be used at the extruder hopper. Workers in the loading area are typically expected to wear personal protective equipment consisting of overalls (including head covering), safety glasses and half-face respirator

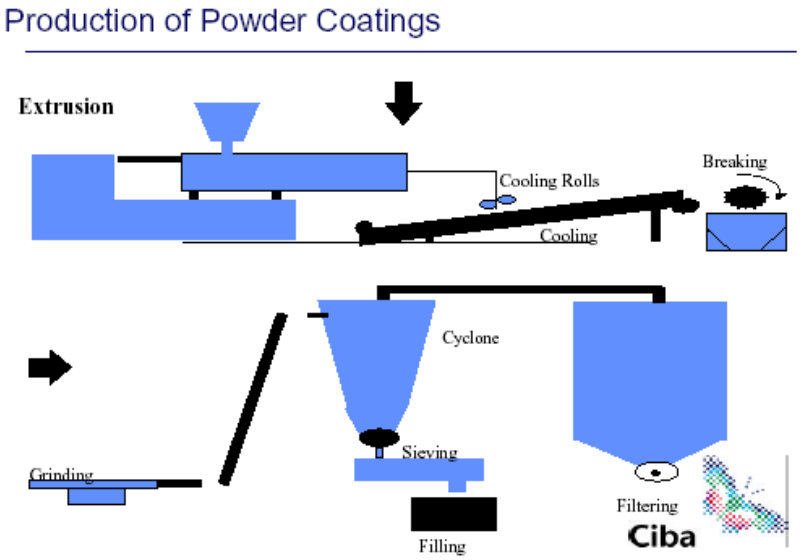
For production of intermediate masterbatch granules, the masterbatch will be extruded as strings that will be chopped into granules in a pelletiser and stored in a hopper ready for storage before bagging. Extrusion moulded products are typically carried along a conveyor, cooled and cut to the desired lengths before being packed for transport.

Routine machinery upkeep and repair is conducted by maintenance workers as needed.

Powder Coatings

See flow diagram below.





At the customer site the notified chemical will be weighed out manually and blended with pigment, hardener and resin and go through pre-grinding, mixing, extrusion, grinding and sieving stages to produce a powder coating resin. The addition of the notified chemical to the powder resin coating is 0.5 – 1.0%. The notified chemical is reacted into the polymer matrix at the extrusion stage. After pre-grinding, or grinding of the extruded material the average particle size will be approximately 35 µm. The process is largely enclosed and automated, with only the weighing of the notified chemical being manual. Local exhaust ventilation is present at the weighing area and workers are expected to wear appropriate PPE such as dust masks, coveralls, gloves and safety glasses.

The powder coating resin will be packed off into 25-kg bags and sold to the white goods appliance market both locally and overseas. The end use application is to prevent the discoloration of items subjected to high temperatures (e.g. gas and electric oven doors).

Specific details of use at the powder coating application facility were not provided. In a typical procedure bags are opened and either emptied into a hopper with an automatic feeder to the production line, or the spray gun is connected directly from the bag. The electrostatically charged powder coating containing the notified chemical (0.5-1.0% reacted into the polymer matrix) is sprayed onto earthed metal objects by means of a spray gun. This application can either be through fully automated and enclosed application lines, by manual spray, or a combination of both (e.g. manual spraying used for touch up of objects). Manual spraying is expected to be conducted in spray booths.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Storage and transport	10 – 20	1 hour per trip or unload / load	20 – 50 times/year
Pre-weigh operators (olefins and polyolefins production)	10 – 25	20 – 40 minutes/day	100 – 150 days/year
Blending and extrusion operators (olefins and polyolefins production)	10 - 25	60 – 120 minutes/day	100 – 150 days/year
Resin Coating Production operators	5 – 10	15 – 30 minutes/day	120 – 180 days/year
Resin Coating Laboratory and Technical personnel	2 – 5	15 – 30 minutes/day	120 – 180 days/year

Exposure Details

Transport and Storage

Waterfront, transport and warehouse workers are not expected to be exposed to the notified chemical except in the case of an accident involving spillage of the notified chemical. Spills are cleaned up by using mechanical handling equipment and scooping into labelled containers.

Masterbatch, Extruder and Resin Powder Coating formulation

During masterbatch, extruder and resin powder coating formulation possible dermal and ocular exposure of workers to spills could occur during charging of the extruder hopper tank or additives hopper tank, taking QC testing samples and when plant and equipment is cleaned. The estimated reasonable worst case and typical case dermal exposure is 3000 mg and 900 mg respectively using measured data for the exposure scenario 'dumping of powders in a formulation facility' (European Commission, 2003). Therefore, for a 70 kg worker and a 10% dermal absorption factor (based on the high molecular weight and high log P_{ow}), reasonable worst-case and typical case dermal exposure is estimated to be 4.3 mg/kg bw/day and 1.3 mg/kg bw/day respectively. The typical case dermal exposure is considered to be more relevant to this exposure scenario (and will therefore be the value used in the risk assessment) due to the relative dustiness of the powder used in the measured scenario and the notified chemical powder, as well as the engineering controls in place. Exposure will be minimised by the personal protective equipment (PPE) expected to be worn by workers during this process – coveralls, eye protection, and impervious gloves.

Inhalation exposure to the granules and dust containing the notified chemical may also occur, but will be limited due to the size of the granules and the enclosed nature of the processes where powder/dust is formed (i.e. during pre-grinding and grinding of the powder coating). Engineering controls such as local exhaust ventilation and the use of respiratory protection will also minimise the exposure.

Extruder operating temperatures during extrusion of both intermediate masterbatches and end-use articles will be monitored by the worker. At recommended processing temperatures, the hot extrusion of polymer containing the notified chemical may produce vapours that may also be inhaled. If the polymer resin is overheated, more extensive decomposition and liberation of irritating carbon oxide fumes may occur. Vapours liberated from hot sections of the extruder will be collected by local exhaust ventilation.

Maintenance workers and laboratory staff may also encounter dermal and ocular exposure during equipment maintenance and testing processes. This exposure is expected to be minimised by the use of coveralls or laboratory coats, eye protection and gloves.

Once the polymer containing the notified chemical is extruded, the latter is bound with in the polymer matrix and is unavailable for absorption.

Powder Coating Application
No specific details were provided for the occupational exposure in a powder coating facility. Typically, inhalation exposure to the fine powder when filling the hopper of a powder coating applicator is expected to be controlled by Local Exhaust Ventilation (LEV) and a dust mask or respirator if necessary. Dermal and occasional ocular exposure is expected to be controlled by the use of gloves and safety goggles.

The potential for worker exposure to the powder coating is low if spraying is fully automated and carried out in an adequately enclosed and ventilated spray booth. Significant exposure may occur when the powder coating is applied manually, but is expected to be limited by the use of adequate ventilation in the spray booth and personal protective equipment, including coveralls, safety glasses, gloves and respiratory protection. There may be some potential for exposure while cleaning up dust residues but as this should be conducted using an industrial vacuum cleaner the majority of the dust should be collected into the vacuum cleaner itself and there should be little atmospheric dust generated. When emptying the vacuum cleaner there is a possibility of dust generation requiring the use of a respirator to control inhalation exposure.

However, while exposure to the powder coating may occur the exposure to the notified chemical is expected to be low due to the low concentration in the powder coating (0.5-1.0%) and because it is reacted into the polymer matrix.

6.1.2. Public exposure

The notified chemical will not be sold to the general public. The public will come into contact with the notified chemical only when it has been incorporated into the polymer and resin coating matrix of finished articles. Consequently, the potential for public exposure to the notified chemical during all phases of its life cycle is considered to be very low.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw low toxicity
Rat, acute inhalation toxicity	not performed
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL 130 mg/kg bw/day
Acute delayed neurotoxicity in Laying Hens	no evidence of neurotoxicity
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Chinese hamster ovary cells	non genotoxic

Acute toxicity
Based on tests in rats the notified chemical exhibits low acute toxicity via oral or dermal exposure.

Irritation and Sensitisation
The notified chemical was slightly irritating to skin when tested in a wetted powder form on rabbits. The notified chemical is slightly irritating to eyes, producing iridial inflammation (1/3 animals), mild conjunctival swelling (1/3 animals), mild corneal opacity (1/3 animals) and moderate conjunctival irritation (3/3 animals). All reactions observed were reversible within 48 hours for 2 of the animals, and within 10 days for the third animal. There was no evidence of reactions indicative of skin sensitisation to the notified chemical when tested on Guinea pigs.

Repeat dose toxicity
In a 28-day repeat dose oral study in rats a decreased adrenal gland weight was noted in females given 350 mg/kg/day or 1000 mg/kg/day. The changes were statistically significant, and as no histopathology was conducted on the adrenal glands the changes could not be discounted as not toxicologically significant. Minor changes in the clinical chemistry and haematology were also observed. The No Observed Effect Level (NOEL) was therefore established as 130 mg/kg bw/day in this study, based on the decreased adrenal weight observed at the higher doses.

Genotoxicity
The notified chemical was not mutagenic to *E. Coli* or *S. Typhimurium*, or clastogenic to Chinese hamster ovary cells under the conditions of the in vitro tests. The notified chemical is therefore not considered to be an in vitro mutagen or genotoxin.

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

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Based on the toxicity data provided for the notified chemical it is a slight eye and skin irritant, and is not a sensitiser. The chemical is not acutely toxic via the oral or dermal routes, but treatment-related effects were seen during chronic exposure. The dermal absorption of the notified chemical is expected to be low based on the hydrophilicity and high molecular weight of the chemical.

Transport and Storage
The risk to the health and safety of transport and storage workers is considered to be low based on the minimal exposure expected.

Masterbatch, Extruder and Resin Powder Coating formulation
During the formulation processes the workers expected to have the highest potential for dermal exposure to the notified chemical are predicted to be those involved in charging the extruder hopper tank or additives hopper tank, taking QC testing samples and cleaning equipment. The dermal exposure for these workers is estimated to be 1.3 mg/kg bw/day. A dermal NOEL was not determined, however a NOEL of 130 mg/kg bw/day was established in a 28-day oral study in the rat. The use of this NOEL results in a margin of exposure (MOE) of 100. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. The MOE is based on conservative assumptions and may overestimate the risk. Therefore, the risk of systemic effects to workers during masterbatch, extruder and resin powder coating formulation is considered acceptable.

However, due to the slight skin and eye irritancy potential of the notified chemical protective gloves and eyewear should be worn during processes when dermal and ocular exposure is possible (i.e. during charging of the extruder hopper tank or additives hopper tank, taking QC testing samples and when plant and equipment is cleaned).

Powder Coating Application
The risk to the health and safety of workers during powder coating application is considered to be low based on: the low concentration of the notified chemical in the powder coating and the fact that the chemical is reacted into the polymer matrix; the low hazard of the notified chemical; and the engineering controls and PPE in use.

6.3.2. Public health

Public exposure to the notified chemical is expected to be negligible and therefore the risk to public health is considered to be negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
There will be no release during manufacture of the chemical as it is not produced in Australia.

Spillage of the notified chemical during transport, storage and processing is expected to be minimal and largely due to accidents. Release to the environment from spills during processing is expected to be negligible, as the material would be collected by sweeping and disposed of to landfill or recovered for production. In addition, stormwater drains in production areas would be fitted with filtration equipment to collect spilled material.

It is estimated that there will be up to 0.5 % (i.e. less than 50 kg/yr) wastage generated from residual material in import fibreboard cartons based on the crystalline nature of the material. This material is likely to be disposed of to landfill.

Total production waste is expected to be up to 3 % (less than 300 kg per annum) and would encompass waste from production start-up and shut-down, accidental spills, cleaning of equipment, reject product and off-cuts. The majority of this wastage would be in the stabilised polymer or resin coating form containing up to 0.2 % or 1 % notified chemical respectively. Waste material containing the notified chemical would be collected by licensed waste disposal contractor and disposed to landfill.

RELEASE OF CHEMICAL FROM USE
Spillage of the reformulated product containing the notified chemical during transport, storage and processing is expected to be minimal and largely due to accidents. The crystals are easily collected and release to the aquatic compartment is unlikely After incorporation into final products, the chemical will be bound in an inert, thermoplastic matrix or resin coating finish and release to the aquatic compartment is not expected.

Residual waste from the imported fibreboard cartons will be disposed to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL
Wastes generated during reformulation and coating application would be disposed of to landfill or incineration. The majority of the notified chemical will share the fate of the plastic articles and white good appliances into which it is incorporated. At the end of the product's useful lifetime, it is expected that disposal will be to either landfill or incineration.

7.1.2 Environmental fate

No environmental exposure of the notified chemical is expected under normal usage as it is not expected to enter soil or aquatic compartments. Most of the notified chemical will be incorporated into the polymer matrix of coatings or finished articles, which upon curing become inert. Once incorporated into the coating formulation or finished articles, the notified chemical is expected to be immobile in the environment. At the end of their useful life, the coated or polymer articles are likely to be either recycled, incinerated, or placed into landfill.

Wastes from spills and usage will go to landfill or be incinerated. Due to the low water solubility of the chemical, it is unlikely to leach from landfill. Once bound within the polymer or resin coating matrix, it is not expected to be mobile. Incineration would destroy the chemical, and typical decomposition products of water and oxides of carbon and phosphorus.

The biodegradability of the notified chemical was investigated in a Ready Biodegradability: Modified Sturm Test (OECD TG 301 B) using bacteria collected from activated sludge from a sewage treatment plant. The reference substance, aniline, attained > 60% degradation by day 14 days, thereby confirming the validity of the test, and attained 85% degradation after 28 days. The notified chemical attained 2% after 28 days and as such, did not pass the test for ready biodegradability, i.e. ≥ 60% biodegradation within 28 days.

Usually COD results form part of the BOD/COD study which gives an indication of possible break-down when a biodegradation study is not available. The COD study provided indicates that if the notified chemical were released to a water body, there is a potential for oxygen depletion within the immediate area.

A study of the potential for the notified chemical to bioaccumulate was conducted following the OECD TG 305C - Bioconcentration: Flow-through fish test. The finding of the study was that the bioconcentration factor was less than 5, indicating the notified chemical is not likely to bioaccumulate.

For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

As it is not expected that the notified chemical will be released to the aquatic compartment, a PEC could not be determined.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. The assessment conclusions are based on the GHS guidance documents (United Nations, 2003). Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 >10.5 mg/L at 96 hours	The notified chemical is not toxic to fish up to the limit of its water solubility.
Daphnia Toxicity	EC50 >8.7 mg/L at 48 hours	The notified chemical is not toxic to daphnia up to the limit of its water solubility.
Algal Toxicity	EC50 >46.9 mg/L at 72 hours	The notified chemical is harmful to algae.
Inhibition of Bacterial Respiration	EC50 >100 mg/L	The notified chemical is slightly toxic to aerobic bacteria.

7.2.1 Predicted No-Effect Concentration

Aquatic ecotoxicity data were provided for four trophic levels. No effects were observed for fish,

algae and sewage microorganisms up to the notified chemical's water solubility, and minor effects were observed for Daphnia. The following Predicted No-Effect Concentration has been calculated using an assessment factor of 100 and based on the lowest EC50 value to the limit of the water solubility of the notified chemical (i.e. for Daphnia).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 for Daphnia	>8.7	mg/L
Assessment Factor	100	
PNEC:	>87	µg/L

7.3. Environmental risk assessment

Since no PEC could be estimated it is not possible to determine the risk quotient (PEC/PNEC).

The notified chemical is not expected to pose a significant hazard to the environment. The usage patterns indicate that the levels of release of the chemical to the environment will be low. Under normal usage there will be no release into the aquatic or soil environments. The majority of the notified chemical will be combined with other coating or polymer components to form a very high molecular weight and stable coating or polymer matrix which will be inert.

8. CONCLUSIONS – SUMMARY OF RISK ASSESSMENT FOR THE ENVIRONMENT AND HUMAN HEALTH

8.1. 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 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.

	Hazard category	***Hazard statement***
Environment	Chronic Category 4	May cause long lasting harmful effects to aquatic life.

8.2. Environmental risk assessment

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

8.3. Human health risk assessment

8.3.1. Occupational health and safety

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

8.3.2. Public health

When used in the proposed manner the risk to the public is considered to be acceptable.

9. MATERIAL SAFETY DATA SHEET

The MSDS of the notified chemical provided by the notifier was reviewed by NICNAS and is published here as a matter of public record. The accuracy of the information on the MSDS

remains the responsibility of the applicant. The MSDS was found to be in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003).

10. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Local exhaust ventilation during manual weighing and transfer

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid eye contact
  - Avoid skin contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Protective eyewear
  - Impervious gloves

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

- 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 end users to minimise environmental exposure during use of the notified chemical:
  - Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

- The notified chemical should be disposed of to landfill or by incineration.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment and collection (eg sweeping). The collected material should be recycled, if possible, or disposed of to landfill.

11. REGULATORY OBLIGATIONS

This risk assessment is based on the information available at the time of notification. If the circumstances under which the notified chemical was assessed change a reassessment may be needed. Under the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as

well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of 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

- the function or use of the chemical has changed from a processing stabiliser for coating resins (powder coatings), polyolefins and olefin copolymers, or is likely to change significantly;
- the amount of chemical being introduced has increased from 10 tonnes, or is likely to increase, significantly;
- if the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

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APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

Melting Point 90.0°C

METHOD In-house method.
Remarks The melting point was determined by differential scanning calorimetry and was conducted in compliance with GLP.
TEST FACILITY Ciba-Geigy Ltd (1992e)

Boiling Point > 358°C at 101.3 kPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Differential scanning calorimetry was used and the study was GLP compliant. An exothermic decomposition was observed from 358°C.
TEST FACILITY Ciba-Geigy Ltd (1995a)

Density 1050 kg/m^3 at 23°C

METHOD EC Directive 84/449/EEC A.3 Relative Density.
Remarks Density measured using the air comparison pycnometer method using Helium (>99.8%) as test gas. The temperature during the measurement was 23°C in deviation from the 20°C recommended in the EEC test guideline. The study was GLP compliant.
TEST FACILITY Ciba-Geigy Ltd (1992f)

Vapour Pressure 9 x 10^{-6} Pa at 25°C

METHOD OECD TG 104 Vapour Pressure.
Remarks The thermobalance method was used. This is a deviation from the Guideline, which recommends gas saturation method for the lowest range. The testing facility provided a reference to support the choice of method. The vapour pressure at 25°C was extrapolated from measured data. GLP compliant
TEST FACILITY Ciba-Geigy Ltd (1992g)

Water Solubility < 2 x 10^{-5} g/L at 20°C (below detection limit of equipment of 2 x 10^{-5} g/L)

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method
Analytical Method: Liquid chromatography with acetonitrile as mobile phase.

The column method was not used as a change in crystal structure might have occurred during deposition of the test substance onto the support material.
TEST FACILITY Ciba-Geigy Ltd (1992h)

Hydrolysis as a Function of pH Could not be performed.

Remarks As described in the report on the water solubility of this test substance, the water solubility is less than 0.02 mg/L and attempts to develop a more sensitive analytical method had been unsuccessful.

It is unlikely that the notified chemical would undergo hydrolysis in the environmental pH range of 4-9.
TEST FACILITY Ciba-Geigy Ltd (1993a)

Partition Coefficient (n-octanol/water) log Pow at 20°C = ≥ 12 (calculated)

METHOD OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method Annex: P_{ow} Calculation methods
Remarks Analytical Method: None
Method entails the calculation of log P_{ow} by the fragmentation of the molecule into suitable substructures with known log P_{ow} values. Computer program CLOPv 3.42 was used.
TEST FACILITY Ciba-Geigy Ltd (1992i)

Adsorption/Desorption – screening test log K_{oc} >> 5.6 at 20°C.

METHOD OECD 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography

Remarks The determination of the adsorption coefficient (log K_{oc}) of the notified chemical on soil by means of a HPLC-screening method showed it is only possible to make the estimation of the above result, as the retention time of the test substance was outside the calibration range. Seven (7) reference substances with log K_{oc} ranging from 3.16 for 1,2,3-trichlorobenzene to 5.63 for 4,4'-DDT, were used to establish the calibration range.
TEST FACILITY Fraunhofer-IUCT (1996)

Dissociation Constant Could not be performed due to the low water solubility of the notified chemical. The chemical formula/structure indicates that it would not have a pK in an accessible range.
Test Facility Novartis Services (1998)

Particle Size MMD = 186 µm

METHOD In house method.

Range (µm)	*Mass (%)*
> 800	0.6
> 400	13
> 315	27
> 200	45
> 100	82
> 63	92
> 40	98

Remarks The study could not be performed in accordance with OECD Test Guideline 110 as the particle size distribution is too large to be analysed by any of the suggested methods. The test was performed using the sieving method. The results are an average of 3 analyses. GLP compliant.
TEST FACILITY Ciba-Geigy Ltd (1992j)

Flammability Limits Not considered highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks In the preliminary test ignition with a hot platinum wire resulted in melting of the test stubstance. The molten substance did not sustain a flame. Therefore the main test was not conducted. GLP compliant.
TEST FACILITY Ciba-Geigy Ltd (1992k)

Autoignition Temperature No self-ignition temperature detected

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

Remarks	The only deviation from the test protocol was that a defined air stream of 2 L/min was circulated through the oven rather than natural air circulation. No significant observations below the melting point of the substance (90°C). GLP compliant.
TEST FACILITY	Ciba-Geigy Ltd (1992l)

Explosive Properties Not considered an explosive.

METHOD	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	The notified chemical is not considered an explosive, based on the test results from: • Thermal sensitivity (effect of a flame) • Mechanical sensitivity (shock) • Mechanical sensitivity (friction) The study was GLP compliant.
TEST FACILITY	Ciba-Geigy Ltd (1992m)

Oxidising Properties Not considered an oxidizing substance

METHOD	EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks	The maximum burning rate of the test substance/cellulose mixture was less than the maximum burning rate of the reference mixture (barium nitrate/cellulose). The study was GLP compliant.
TEST FACILITY	Ciba-Geigy Ltd (1992n)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD
- Species/Strain: Rat/ Tif RAI f1 (SPF)
- Vehicle: Oleum arachidis Ph.H.VI
- Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 M	2000	0
II	5 F	2000	0

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: Piloerection, hunched posture, dyspnea and reduced locomotor activity were observed in all animals. The animals recovered within 4 to 5 days.
- Effects in Organs: No deviations from normal morphology were found.

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

TEST FACILITY: Ciba-Geigy Ltd (1992o)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical

METHOD
- Species/Strain: Rat/Tif RAI f1 (SPF)
- Vehicle: Oleum arachidis pH.H.VI
- Type of dressing: Semi-occlusive.
- Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 M	2000	0
II	5 F	2000	0

- LD50: > 2000 mg/kg bw
- Signs of Toxicity - Local: Piloerection was observed in all animals. All animals recovered within 1 day.
- Signs of Toxicity - Systemic: None.
- Effects in Organs: No deviations from normal morphology were found.

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

TEST FACILITY: Ciba-Geigy Ltd (1992p)

B.3. Acute toxicity – inhalation

Not performed.

B.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 (Chbb:NZW)
Number of Animals	3
Vehicle	Distilled water used to moisten patches before application
Observation Period	72 h
Type of Dressing	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	1	< 24 hours	0
Oedema	0	0	0	0	-	0

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

Remarks – Results	Very slight erythema was observed in one animal at 1 hour. The reaction had cleared by the 24 hour observation point.
CONCLUSION	The notified chemical is slightly irritating to skin.
TEST FACILITY	Ciba-Geigy Ltd (1992q)

B.5. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 84/449/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	10 days
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	1.33	0.33	0.33	2	< 10 days	0
Conjunctiva: chemosis	0.33	0	0	1	< 48 hours	0
Conjunctiva: discharge	-	-	-	-	-	-
Corneal opacity	0.33	0	0	1	< 48 hours	0
Iridial inflammation	0.67	0	0	1	< 72 hours	0

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

Remarks - Results	The eye reactions observed were reversible within 48 hours for animals 2 and 3, and within 10 days for animal 1.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Ciba-Geigy Ltd (1992r)

B.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation – Magnuson and Kligman Method. EC Directive 84/449/EC B.6 Skin Sensitisation - Magnuson and Kligman Method.
Species/Strain	Guinea pig/Pirbright White Strain (Tif: DHP)
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 5% topical: 50% (maximum dose tested)
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: intradermal: 5% topical: 50% in vaseline
Signs of Irritation	No test substance related irritation was observed.
CHALLENGE PHASE	
1st challenge	topical: 50% in vaseline
2nd challenge	Not performed.
Remarks - Method	As no skin irritation was observed in the pretest the epidermal application site was pretreated with 10% sodium lauryl sulphate 24 hours prior to epidermal 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	50%	0/20	0/20	-	-
Control Group	50%	0/10	0/10	-	-

Remarks - Results	Under the experimental conditions employed none of the animals of the test group showed skin reactions 24 and 48 hours after removing the dressings.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Ciba-Geigy Ltd (1993b)

B.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	In-house method, similar to: 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/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 0 days
Vehicle	Peanut oil
Remarks - Method	The CIT in-house method deviated from the OECD Guideline 407 as follows:

- the number of animals used was 8/dose rather than 10/dose;
- the epididymides and the brain were not weighed;
- the blood clotting time/potential and haematocrit levels were not measured;
- sodium, potassium and total protein and albumin values in the blood were not determined.
- Full histopathology was only carried out in the kidney and liver of all animals in the control and test groups (other organs examined in selected animals only).

Despite these deviations from the OECD Guideline the study was considered to be valid for determination of the toxic effects after repeated exposure to the notified chemical. However the lack of full histopathology influenced the determination of the NOAEL.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	4 M, 4 F	0	0
II (low dose)	4 M, 4 F	50	0
III (mid dose)	4 M, 4 F	130	0
IV (mid dose)	4 M, 4 F	350	0
V (high dose)	4 M, 4 F	1000	0

Mortality and Time to Death

No mortalities occurred during the treatment period.

Clinical Observations

No clinical signs, in particular no signs which could be related to a neurotoxic effect, were observed during the treatment period. There were considered to be no treatment related effects on body weight.

Laboratory Findings

Clinical Chemistry

Slight differences from control values were noted in week 4 for the aspartate aminotransferase and plasma butirylcholinesterase values in the treatment groups. However these changes did not show any dose relationship and were therefore considered not to be treatment-related.

Haematology

In week 4 a slightly higher haemoglobin level was noted in males and females given 350 and 1000 mg/kg/day, when compared to the control values. The increase in females was dose related. Also seen in the animals given 350 and 1000 mg/kg/day was a slight increase in mean cell volume and mean cell haemoglobin in males, and a slight and dose related increase in erythrocyte count and packed cell volume in females. Some slight differences in white cell count (increased neutrophils and eosinophils, decreased lymphocytes) were also noted in females given 350 and 1000 mg/kg bw/day. However, as these differences were minor and not statistically significant they were not considered to be toxicologically significant.

No differences from control values were noted for any other haematological parameter.

Effects in Organs

Organ weights

A statistically significant lower mean absolute adrenal gland weight was noted in females given 350 mg/kg/day (-18%) or 1000 mg/kg/day (-19%) when compared to respective controls.

A statistically significant lower mean relative spleen weight was noted in females given 130 mg/kg/day. However, as this decrease was not found in the females of the higher dose groups it was not considered to be treatment- related.

No other differences from controls were noted in the treated groups.

Macroscopic findings
Liver enlargement was noted in 1/4 males given 130 mg/kg/day. However, as this finding was not recorded in the higher dose groups, and it was not associated with any relevant histopathological changes, it was considered not to be treatment-related.

All other findings were considered to not be treatment-related as they are those which are commonly recorded as spontaneous changes in untreated laboratory rats of this strain.

Microscopic findings
A moderate zonal coagulative hepatocellular necrosis, together with a moderate neutrophil infiltration, was noted in the liver of one male treated at 50 mg/kg/day. The finding was considered to be spontaneous and to be not treatment-related.

All other findings were considered to not be treatment-related as they are those which are commonly recorded as spontaneous changes in untreated laboratory rats of this strain.

Remarks – Results
No histopathology was carried out on the adrenal glands. Therefore it can not be discounted that the decreased adrenal weights observed in females given 350 and 1000 mg/kg bw/day is a treatment related effect.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 130 mg/kg bw/day in this study, based on the decreased adrenal weight observed at the higher doses.

TEST FACILITY Centre International de Toxicologie (C.I.T.) (1993)

B.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, TA98, TA100. *E. coli*: WP2 uvrA.
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 312.5 - 5000 µg/plate. b) Without metabolic activation: 312.5 - 5000 µg/plate.
Vehicle	Acetone
Remarks - Method	No significant protocol deviations. The preliminary toxicity test was carried out with strains *S. typhimurium* TA100 and *E. coli* WP2 uvrA with and without metabolic activation.

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	312.5 µg/plate	negative
Test 2	-	> 5000 µg/plate	312.5 µg/plate	negative
Present				
Test 1	> 5000 µg/plate	> 5000 µg/plate	312.5 µg/plate	negative
Test 2	-	> 5000 µg/plate	312.5 µg/plate	negative

Remarks - Results	The notified chemical did not induce gene mutations in the strains of *S. typhimurium* and *E. coli* either with or without metabolic activation. Positive controls confirmed the sensitivity of the test system. The presence of precipitates was not considered to have affected the quality or the integrity of the data.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Ciba-Geigy Ltd (1992s)

B.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.
Species/Strain	Chinese hamster
Cell Type/Cell Line	ATCC CHO CCL 61 (ovary, Chinese hamster, CHO K1)
Metabolic Activation System	Post mitochondrial fraction S9 from Aroclor 1254 induced rat liver
Vehicle	Acetone
Remarks - Method	No significant protocol deviations. The cytotoxicity test was performed as an integral part of the mutagenicity test rather than as a preliminary test.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	3.91, 7.81, 15.63, 31.25, 62.50, 125*, 250*, and 500*	18 hours	18 hours
Test 2	31.25, 62.50, 125*, 250*, and 500*	18 hours	18 hours
Test 3	3.91, 7.81, 15.63, 31.25, 62.50, 125*, 250*, and 500*	42 hours	42 hours
Present			
Test 1	3.91, 7.81, 15.63, 31.25, 62.50, 125*, 250*, and 500*	3 hours	18 hours
Test 2	31.25, 62.50, 125*, 250*, and 500*	3 hours	18 hours
Test 3	3.91, 7.81, 15.63, 31.25, 62.50, 125*, 250*, and 500*	3 hours	42 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	-	> 500 µg/mL	31.25 µg/mL	negative
Test 2	-	> 500 µg/mL	31.25 µg/mL	negative
Test 3	-	> 500 µg/mL	31.25 µg/mL	negative
Present				
Test 1	-	> 500 µg/mL	31.25 µg/mL	negative

Test 2	-	> 500 µg/mL	31.25 µg/mL	negative
Test 3	-	> 500 µg/mL	31.25 µg/mL	negative

Remarks - Results: In Test 1 in the presence of metabolic activation, at the highest concentration (500 µg/mL), a slight but statistically significant increase in specific chromosomal aberrations was observed. However, the incidence of metaphases with aberrations was within the historical negative control range and the criteria for a positive response was not fulfilled. The observed specific chromosomal aberrations were therefore considered to be spontaneous in origin and not related to treatment.

The positive controls confirmed the sensitivity of the test system.

CONCLUSION: The notified chemical was not clastogenic to Chinese hamster ovary cells treated in vitro under the conditions of the test.

TEST FACILITY: Ciba-Geigy Ltd (1993c)

B.10. Neurotoxicity

TEST SUBSTANCE: Notified chemical

METHOD: OECD 418 - Delayed Neurotoxicity of Organophosphorus Substances Following Acute Exposure.

Remarks – Method: The study deviated from the OECD protocol as no biochemical studies were conducted. Also, as these studies were not carried out the number of animals used in each group was reduced from 12/group to 4 in the control group and 8 in the treatment group.

RESULTS

Remarks – Results: The notified chemical administered orally in two doses of 2000 mg/kg did not produce clinical, macropathological or micropathological signs of neurotoxicity.

CONCLUSION: The notified chemical was not neurotoxic to laying hens under the conditions of the test.

TEST FACILITY: Ciba-Geigy Ltd (1991)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Bacteria collected from activated sludge of Ciba sewage treatment plant.
Exposure Period	28 days
Auxiliary Solvent	Emulsifier (polyoxyethylene-sorbitan-mono-oleate (TWEEN 80) solution)
Analytical Monitoring	HPLC
Remarks – Method	No significant protocol deviations. Test concentrations: 10.5 mg/L and 20.9 mg/L Reference material: Aniline at 20 mg/L Blank: water with 15 ml of polyoxyethylene-sorbitan-mono-oleate (TWEEN 80) solution Each treatment was done in duplicate.

RESULTS

Test substance (10.5 mg/L)		*Test substance (20.9 mg/L)*		*Aniline*	
Day	*% degradation*	*Day*	*% degradation*	*Day*	*% degradation*
3	-1	3	0	3	0
6	0	6	0	6	0
9	0	9	0	9	31
13	0	13	0	13	67
16	0	16	0	16	74
20	1	20	0	20	78
23	1	23	0	23	81
28	2	28	1	28	85

Remarks - Results	After 28 days, the test substance at concentrations 10.5 and 20.9 mg/L reached a mean degradation of 2% and 1% respectively. The reference substance reached a degradation of greater than 60% by day 13 and 85% by day 28, therefore indicating the test was valid.
CONCLUSION	The notified chemical cannot be classed as ready biodegradable.
TEST FACILITY	Ciba-Geigy Ltd (1992t)

C.1.2. Bioaccumulation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 305C Bioconcentration: Flow-through Fish Test. EC Directive 98/73/EC C.13 Bioconcentration: Flow-Through Fish Test.
Species	*Cyprinus carpio*
Exposure Period	Exposure: 56 days Depuration: None
Auxiliary Solvent	None
Concentration Range Nominal	0.1 and 1.0 µg/mL
Concentration Range Actual	Not given
Analytical Monitoring	HPLC
Remarks – Method	No significant protocol deviations. Flow rate: 432 L/day

	Dissolved oxygen: - in test conc. 0.1 µg/mL, 6.9-7.8 µg/mL; and, - in test conc. 1.0 µg/mL, 7.0-7.6 µg/. Temperature: 24.8 ±0.7°C
RESULTS	
Bioconcentration Factor	< 5 (8 weeks)
CT50	
Remarks - Results	The notified chemical has a bioconcentration factor less than 5 after 8 weeks and is not accumulative in fish.
CONCLUSION	The notified chemical is slightly bioconcentrating (Mensink, 1995).
TEST FACILITY	Institute of Ecotoxicology (1996)

C.1.3. Chemical oxygen demand (COD)

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 84/449/EEC C.9: Chemical Oxygen Demand
Oxidant	Potassium dichromate
Exposure Period	2 hours
Auxiliary Solvent	Sulphuric acid containing silver sulfate
Analytical Monitoring	METTLER Memotitrator
Remarks – Method	The test substance was dissolved in sulphuric acid containing silver sulphate instead of water. The required amount of water was added subsequently. Reference substance: potassium hydrogen phthalate. Titration solution: ammonium iron-II-sulfate (0.12 mol/L) Temperature: 148 ± 3°C
RESULTS	
Remarks – Results	Test substance: 2.44 g COD/g Reference substance: 194.7 mg COD/L
TEST FACILITY	Ciba-Geigy Ltd (1992u)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static test
Species	Zebra-Fish (*Brachydanio rerio*)
Exposure Period	96 h
Auxiliary Solvent	1-methyl-2-pyrrolidone and polyoxyethylene-sorbitan-monooleate
Water Hardness	184 mg $CaCO_3$/L
Analytical Monitoring	GC
Remarks – Method	The stock solution (10% w/w) was prepared by the mixing of 10 g of test substance and 10 g of the 1-methyl-2-pyrrolidone and polyoxyethylene-sorbitan-monooleate mixture by a marble mill for 24 hours. Then 8 g of the resultant mixture was mixed with 32 g of water. All concentrations were homogenous with no observed undissolved test substance, except for the concentration 100 mg/L. At 100 mg/L solid material was observed on the surface at the commencement of the study and then at the bottom on completion. Solution samples were taken from the centre of each test vessel prior to exposure and after 96 hours exposure for later analysis by

GC. Details of the analysis method have not been provided.

Photoperiod : 16 hours daily (fluorescent light)
Temperature, pH and oxygen concentration were measured at 0, 24, 48, 72 and 96 hours.
Temperature: 23±1°C
pH: 7.9 – 8.4
Oxygen concentration ranged from 28% (48 hours highest conc) to 98%. After 48h of exposure, the O_2 concentration was too low. Therefore, a gentle aeration was performed.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual after 96 h*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
10	0.6	10		0	0	0	0
18	0.8	10		0	0	0	0
32	1.7	10		0	0	0	0
58	1.7	10		0	0	0	0
100	10.5	10		0	0	0	0

LC50	> 10.5 mg/L at 96 hours.
NOEC	10.5 mg/L at 96 hours.
Remarks – Results	Values are based on measured end concentrations. The fish did not exhibit any abnormal behaviours during the study.

CONCLUSION The notified chemical is not toxic to fish up to the limit of its water solubility.

TEST FACILITY Ciba-Geigy Ltd (1992v)

C.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – 48h Static Test

Species	*Daphnia magna Straus 1820*
Exposure Period	48 hours
Auxiliary Solvent	1-methyl-2-pyrrolidone and polyoxyethylene-sorbitan-monooleate
Water Hardness	240 mg $CaCO_3$/L
Analytical Monitoring	GC
Remarks – Method	No significant protocol deviations.

The stock solution was prepared by the mixing of 10 g of test substance and 10 g of the 1-methyl-2-pyrrolidone and polyoxyethylene-sorbitan-monooleate mixture by a marble mill for 24 hours. Then 1 g of the resultant mixture was mixed with 4 g of water, with 1.96 mL of the resultant water solution mixed with and made up to a volume of 2000 mL. Undissolved test material was observed on the surface and at the bottom of the test solution. Composite samples were taken from the centre of each test vessel prior to exposure and after 48 hours exposure for later analysis by GC. Details of the analysis method have not been provided.

Photoperiod : 16 hours daily (fluorescent light)
Temperature, pH and oxygen concentration were measured at 0,and 48

hours.
Temperature: 20 to 23 ±1ºC
pH: 7.8 – 8.2
Aeration: 24 hours prior to commencement, then none. Oxygen concentration ranged from 95% to 103%.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual after 48 h*		*24 h*	*48 h*
10	0.5	20	0	0
18	1.3	20	0	0
32	1.9	20	0	0
58	8.7	20	0	0
100	6.6	20	0	1

LC50	> 8.7 mg/L at 48 hours
NOEC	8.7 mg/L at 48 hours
Remarks – Results	Values are based on measured end concentrations.

CONCLUSION The notified chemical is not toxic to daphnia up to the limit of its water solubility.

TEST FACILITY Ciba-Geigy Ltd (1992w)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE

METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range Nominal	1.23 – 100 mg/L
Concentration Range Actual	0.2 – 46.9 mg/L
Auxiliary Solvent	1-methyl-2-pyrrolidone and polyoxyethylene-sorbitan-monooleate
Analytical Monitoring	GC
Remarks - Method	No significant protocol deviations.

The stock solution was prepared by the mixing of 4 g of test substance and 4 g of the 1-methyl-2-pyrrolidone and polyoxyethylene-sorbitan-monooleate mixture by a marble mill for 24 hours. Then 1 g of the resultant mixture was mixed with 4 g of water, with 1.96 mL of the resultant water solution mixed with and made up to a volume of 1000 mL. All concentrations were homogenous and do not appear to have had any undissolved test substance present. Composite samples were taken from the centre of each test vessel prior to exposure and after 72 hours exposure for later analysis by GC. Details of the analysis method have not been provided.

Test concentrations were done in triplicate and there were 6 blank controls.
Temperature: 23 ± 2ºC
Lighting: continuous illumination, approximately 8000 lux.
pH was measured at 0 and 72 hours: 7.8-8.3.
Cell density was measured at 24, 48 and 72 hours.

RESULTS

Remarks - Results	EbC 50 (0 – 72 h): > 46.9 mg/L NOEbC (0 – 72 h): 46.9 mg/L Values are based on measured end concentrations.
CONCLUSION	The notified chemical is harmful to algae.
TEST FACILITY	Ciba-Geigy Ltd (1992x)

C.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 sludge from sewage treatment plant
Exposure Period	3 hours
Concentration Range Nominal	1.3 – 102.4 mg/L
Remarks – Method	Instead of a centrifuged sludge a settled sludge was used. Due to the poor solubility of the test substance at test concentrations, no stock solution was prepared. The test substance was given directly into the medium. Therefore, a constant factor between the test concentrations could not be achieved. Reference substance: 3,5-Dichlorophenol – 3.2. 10.0 and 32.1 mg/L. Sludge concentration: 1.59 g/L dw. Temperature 20 ±2ºC. Measurement: oxygen consumption per hour (mg/L) via Orion – Electrode.
RESULTS	
EC50	> 100 mg/L
NOEC	100 mg/L
Remarks – Results	Results were all graphically determined. EC50 for the reference substance was 13.1 mg/L,
CONCLUSION	The notified chemical is slightly toxic to aerobic bacteria.
TEST FACILITY	Ciba-Geigy Ltd (1992y)