File No: STD/1256

July 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Pigment Orange 767B in IRGAZIN® DPP Cosmoray Orange

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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Pigment Orange 767B in IRGAZIN® DPP Cosmoray Orange

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; Molecular Weight; Spectral Data; Purity; Identity of Toxic or Hazardous Impurities; % Weight of Toxic or Hazardous Impurities; Non-Hazardous Impurities; Identity of Additives / Adjuvants; % Weight of Additives / Adjuvants; Import Volume; Identity of Customer Sites

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Notified to the following countries during late 2006/early 2007:
EU; USA; Japan; Canada; Korea; Philippines; China

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Pigment Orange 767B (notified chemical)
Experimental Orange 107 (IRGAZIN® DPP Cosmoray Orange)
Pigment Orange 107 (IRGAZIN® DPP Cosmoray Orange)

MARKETING NAME(S)
IRGAZIN® DPP Cosmoray Orange
Experimental Orange RL 107
(all contain 40-50% of the notified chemical)

ANALYTICAL DATA

ANALYTICAL METHOD	IR Spectra Mass Spectrometry GC Chromatogram HPLC UV/Vis
Remarks	Spectra data were provided
TEST FACILITY	Ciba Specialty Chemicals, Inc (2005a, b, c) Notox B.V. (2006a)

3. COMPOSITION

IRGAZIN® DPP Cosmoray Orange contains two major components including the notified chemical. The proportion of the notified chemical in IRGAZIN® DPP Cosmoray Orange is 40-50%.

4. PHYSICAL AND CHEMICAL PROPERTIES

All tests below were conducted using the imported product IRGAZIN® DPP Cosmoray Orange.

Appearance at 20ºC and 101.3 kPa Orange powder with no odour (for IRGAZIN® DPP Cosmoray Orange)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	>400ºC	Measured
Boiling Point	>400ºC	Measured
Density	1600 kg/m^3 at 20ºC	Measured
Vapour Pressure	(3.5 ± 0.5) x 10^{-5} kPa at 20ºC	Measured
Water Solubility	<4.99 x 10^{-4} g/L at 20ºC	Measured
Hydrolysis as a Function of pH	Not determined	Insufficient solubility in water to permit testing.
Partition Coefficient (n-octanol/water)	log Pow = 4.5 – 4.7 at 20ºC	Measured
Adsorption/Desorption	log K_{oc} = 4.95 at 35°C	Measured
Dissociation Constant	Not applicable	No dissociable functionality
Particle Size	Inhalable fraction (<100 μm): 100% Respirable fraction (<10 μm): <50% MMAD = approx. 49 μm	Measured
Flash point	Not applicable	A low volatility solid
Flammability	Not highly flammable	Measured
Autoignition Temperature	>400ºC	Measured
Explosive Properties	Not explosive	Estimated

Discussion of Observed Effects

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

Reactivity

Stable under normal conditions of uses.

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 will not be manufactured in Australia. It will be imported by sea as a 40 - 50% component of IRGAZIN® DPP Cosmoray Orange.

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

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

PORT OF ENTRY

Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

Ciba Specialty Chemicals Pty Ltd and paint manufacturers in VIC

TRANSPORTATION AND PACKAGING
IRGAZIN® DPP Cosmoray Orange containing 40-50% of the notified chemical is imported into Australia by ship in powder form in 20 kg robust UN approved fibreboard cartons, with 2 inner PE-lined paper bags. The product is then transported from the dockside to the Ciba Specialty Chemicals warehouse by road/rail, where it is stored until required for despatch to customers. No repacking of the imported product is expected to take place before reformulation. The formulated final product is packaged in 200L drums.

USE
Colourant for automotive OEM basecoats.

OPERATION DESCRIPTION
Paint formulation
Laboratory scale
The ingredients required for making the paint, including the notified chemical, are combined in a container in the laboratory under stirring. The paint (containing <5% notified chemical) is then sprayed onto panels in a spraybooth. The panels are baked in an oven and the finished paint film is subjected to various tests.

Production scale
The pigment powder (containing 40 – 50 % notified chemical) is weighed out on a weighing scale and then manually added into a closed mixer. Following mixing with other ingredients, approximately 500 mL of the formulated paint (containing <5% notified chemical) is sampled for testing. When approved the formulated paint is filled through dedicated pipework and filling equipment into closed head 200L drums. The filling equipment automatically places a short fill pipe through the bung hole in the top of the drum and fills the drum.

QC testing
The operator adjusts the paint containing the notified chemical and sprays panels for baking and testing. Several tests such as solids, viscosity and weight per litre are performed on the wet paint.

Paint application
The 200 L drums of paint (containing <5% notified chemical) are pumped into the circulating mix tank using a dedicated lance, pipework and pump. Once in the tank, solvent is added to adjust the paint to application viscosity. This paint is pumped around a circulation system from which it is sprayed onto car bodies by robots and operators in a dedicated ventilated spray area. Operators spray the paint onto specific areas of the car that are not painted by the robots. The painted cars travel through an oven where the notified chemical is incorporated in the final paint film on the car. During production breaks, operators use cloth dampened with solvent to clean residual paint from the spray equipment.

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*
Transportation and Storage	4 - 6	1 – 2 hours per day	10 – 20 days per year
Laboratory work & QC Testing	6 – 10	6 – 8 hours per day	60 – 80 days a year
Paint formulation	10 – 30	4 hours per day	200 days per year
OEM Automotive Sites – add to circulation tank	10 – 20	2 hours per day	200 days per year
OEM Automotive Sites – Hand spray pick up	20 – 30	8 hours per day	200 days per year
OEM Automotive Sites – Cleaning of spray equipment	10 – 20	2 hours per day	200 days per year

Exposure Details

Paint formulation

There is potential for dermal, ocular and inhalation exposure to the notified chemical at a level of 40 – 50 % during opening the fibreboard carton and transfer of the pigment to the mixing container. Potential exposure could also occur if excess material spills onto the weigh scale. There is potential for dermal exposure to the notified chemical at a level of < 5% during sampling and testing of the paint formulation. There is the additional potential for inhalation exposure to paint droplets during spray application for QC testing. Following formulation of the paint, dermal, ocular and inhalation exposure to the notified chemical at a concentration of < 5% could occur during transfer and spray application of the paint formulation or contact with the wet paint surface. However, these processes are typically undertaken under local exhaust ventilation or in spray booths where appropriate extraction are available. Moreover, workers are typically provided with appropriate PPE (glasses, gloves, dust mask, coveralls).

Paint application

Workers' exposure to the notified chemical at a level of < 5% would be minimal during automated spray painting as this occurs in a dedicated ventilated spray area by robots. However, dermal, ocular and inhalation could occur during paint transfer into the circulating mix tank, manual spray applications, and during cleaning. Workers are required to wear full protective clothing and vapour masks that filter atomised paint out of the air they inhale.

Once the paint surface has been cured the notified chemical is bound within an inert matrix and therefore will be unavailable for exposure.

6.1.2. Public exposure

The notified chemical will not be directly available to the public. The notified chemical is used in an automotive paint that is cured prior to reaching the public. Therefore, although the public will come into contact with the exterior of car bodies, the notified chemical will not be available for exposure.

6.2. Human health effects assessment

The results from toxicological investigations conducted are summarised in the table below. Details of these studies can be found in Appendix B. All tests were conducted using the imported product IRGAZIN® DPP Cosmoray Orange.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	low oral toxicity LD50 >2000 mg/kg bw
Rat, acute dermal toxicity	low dermal toxicity LD50 >2000 mg/kg bw
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL 150 mg/kg/day in males NOAEL 1000 mg/kg/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic

The notified chemical was found to be slightly irritating to the eyes. The NOEL in a 28-day oral repeat dose study in rats was 150 mg/kg bw/day in males on the basis of isolated treatment-related clinical chemistry changes.

An acute inhalation study was not performed on the notified chemical. The notifier has justified the absence of this test by stating that users of the colourant containing the notified chemical are likely to minimise its wide dispersion during manual handling procedures in order to avoid intensive cleaning of the equipment when changing to a different colour.

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

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Acute toxic potential

Dermal, ocular and inhalation are the main routes of worker exposure to the notified chemical during manual handling of the pigment containing the notified chemical at concentrations of 40 – 50%. Similar exposure may occur to the paint formulation containing the notified chemical at concentrations of <5%, such as during manual spray application, transfer into the mixing tank, and cleaning.

Acute effects from exposure to the notified chemical are unlikely to occur, given its low acute toxicity. If dermal exposure occurs, absorption through the skin is not expected to be significant, given its low water solubility (<1 mg/mL), and high partition coefficient (log P >4) (European Commission 2003).

Skin irritation is unlikely to occur during such exposure, given that the notified chemical is non-irritating to the skin. Slight eye irritation may occur when exposed to the chemical at concentrations of 40 – 50%, as the notified chemical is slightly irritating to the eyes in animals. Although it is expected to be minor, eye protection is recommended to reduce the risk of potential eye irritation.

Repeat dose toxic potential

The risk of adverse effects resulting from repeated exposure to the notified chemical are unlikely to be significant considering the NOEL is 150 mg/kg bw/day in males. The various control measures in place during all handling of the notified chemical should ensure that exposure levels will be significantly below the NOEL value.

The product containing 40-50% of the notified chemical is 100% inhalable (particle size <100μm) and <50% respirable (particle size <10μm). Given the low water solubility of the notified chemical, any dust that deposits in the nasopharyngeal region (>1-5 μm) could be coughed or sneezed out of the body, or swallowed. Dust depositing in the tracheobronchial region (<1-5 μm) would be mainly cleared from the lungs and swallowed (European Commission, 2003). This will occur to only a small fraction of the dust. However, irritant or toxic effects as a result of inhalation of the notified chemical can not be ruled out, given that acute or repeat dose inhalation toxicity has not been determined. The notifier has stated that several measures are typically in place to minimise inhalation exposure during handling of the notified chemical, including dust extraction (local exhaust ventilation) during manual handling of the powder, performing spraying operations in spray booths, and the wearing of personal protective equipment, including dust masks. EASE modelling has indicated that, in the presence of local exhaust ventilation, the estimated dust exposure would be 2 – 5 mg/m^3, which is below the general exposure standard for dusts of 10 mg/m^3 (NOHSC 1995). However, modelling of a situation in which local exhaust ventilation is not used indicates a predicted dust exposure of 5 – 50 mg/m^3, which is above the exposure standard. This indicates that local exhaust ventilation should be in place during operations involving the notified chemical.

6.3.2. Public health

The risk to the public from exposure to the notified chemical is expected to be negligible, given its non-hazardous nature and the fact that it will be encapsulated within a matrix and not be bioavailable upon occasional contact with the exterior of car bodies.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Release to the environment during shipping, transport and warehousing will only occur through accidentals spills or leaks of the fibreboard cartons.

Spills are expected to be minimal. When spills occur, they will be contained and mixed with a damp absorbent material (to lower dust levels) and sent to a licensed off site waste disposal centre. Empty fibreboard cartons are expected to be either recycled (if packaging is uncontaminated) or sent to approved landfill. Carton residue waste is expected to be less than 1% of imported volume.

Residual waste from the mixing vessel is anticipated to be 0.5% of imported volume. This waste is collected when the mixing vessel is cleaned, and sent to the onsite solvent recovery system. Solid residues from this system can be disposed to approved landfill through a licensed waste contractor.

RELEASE OF CHEMICAL FROM USE
Under normal use procedures, losses of the notified chemical through overspray, mixing of chemicals and cleaning of plant equipment as well as losses from residues in containers have been estimated to be a maximum of 40%, which equates to <1 tonne per annum of notified chemical. Wastes from this application will be hardened and disposed of to landfill.

Empty drums that contained the paint will be sent to drum reconditioners where the waste is incinerated. Residual waste of the notified chemical in paint drums is expected to be 2% of the imported volume.

The remainder of the notified chemical will be cured in conjunction with other components in the paint baking process to form the final paint film. It is not available for direct release to the environment. Disposal of the automobile may be through landfill or recycling, and the fate of the paint will be related to that of the automobile.

RELEASE OF CHEMICAL FROM DISPOSAL
Contaminated fibreboard cartons and empty paper bags that contained the notified chemical are expected to be disposed to approved landfill. It is expected that up to 20 kg of the notified chemical will be disposed of in this manner.

Paint drums containing the notified chemical are sent to a drum recycler where the waste residues are consumed in a high temperature incinerator. It is expected that up to 40 kg of the notified chemical will be disposed of in this manner.

At the reformulation sites, residues from equipment cleaning will be collected and processed to remove the solvent and solidify the remaining components which will be disposed of through a licensed waste contractor. It is expected that up to 10 kg of the notified chemical will be disposed of in this manner.

Residues from overspray generated in the painting operation are collected, treated and solidified. These solid residues are disposed of in approved landfill. It is anticipated that up to 1 tonne of notified chemical will be disposed of in this manner.

In the landfill environment, the notified chemical is expected to be immobile based on its very low water solubility and should associate with soil and organic matter. Over time, it is expected that the notified chemical will eventually degrade via biotic and abiotic processes to form simple organic compounds that may contain nitrogen and/or chlorine.

7.1.2 Environmental fate

The notified chemical was not found to be ready biodegradable. Based on the very low aquatic exposure, the notified chemical is not expected to significantly bioaccumulate. Lack of aquatic exposure is further expected to mitigate any potential. For the details of the environmental fate study please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

Under the proposed use pattern, release to the aquatic environment is not expected at any point in the lifecycle of the notified chemical in Australia. Therefore, it is not possible to calculate a Predicted Environmental Concentration.

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 >100 mg/L (WAF)	Not harmful
Daphnia Toxicity - Acute	EC50 >100 mg/L (WAF)	Not harmful
Daphnia Toxicity - Chronic	EC50 >100 mg/L (WAF)	Not harmful
Algal Toxicity	E_rC50 >100 mg/L (WAF)	Not harmful
Inhibition of Bacterial Respiration	EC50 >100 mg/L (WAF)	Not harmful

WAF = water accommodated fraction

The notified chemical was not found to be harmful to aquatic organisms up to the limit of its solubility in water.

7.2.1 Predicted No-Effect Concentration

Based on the results of the ecotoxicity tests conducted, the following Predicted No-Effect Concentration (PNEC) has been calculated as follows:

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50	>100 (WAF)	mg/L
Assessment Factor	100	
PNEC:	>1 (WAF)	µg/L

7.3. Environmental risk assessment

As it is not possible to calculate a PEC, it is not possible to derive the Risk Quotient (PEC/PNEC). Given the lack of aquatic exposure, and absence of observed ecotoxicity up to the limit of its solubility in water, the risk to the environment posed by the notified chemical is expected to be acceptable under the proposed use pattern.

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 *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

8.2. Human health risk assessment

8.2.1. Occupational health and safety

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable provided that certain control measures are in place.

8.2.2. Public health

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

8.3. Environmental risk assessment

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

9. MATERIAL SAFETY DATA SHEET

The MSDS of the products containing 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 *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:
  - Local exhaust ventilation during manual handling operations
  - Perform all spray operations in spray booths.

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

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Wear respiratory protection when handling IRGAZIN® DPP Cosmoray Orange powder.
  - Wear eye protection.

  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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The notified chemical should be disposed of to landfill.

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

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 colourant for automotive OEM basecoats, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 5 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.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

All tests below were conducted using the imported product IRGAZIN® DPP Cosmoray Orange.

Appearance at 20ºC and 101.3 kPa Orange-red powder with no odour (for IRGAZIN® DPP Cosmoray Orange)

Melting Point/Freezing Point >400 ºC

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Determined by differential scanning calorimetry. Reaction or decomposition of the test substance occurs above 400°C.
TEST FACILITY Notox B.V. (2006b)

Boiling Point >400 ºC

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Determined by differential scanning calorimetry. Reaction or decomposition of the test substance occurs above 400°C.
TEST FACILITY Notox B.V. (2006b)

Density 1600 kg/m^3 at 20ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks A gas pycnometer was used (static method).
TEST FACILITY Notox B.V. (2006c)

Vapour Pressure (3.5 ± 0.5) x 10^{-5} kPa at 20ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks A capacitance manometer was used.
TEST FACILITY Notox B.V. (2006d)

Water Solubility <4.99 x 10^{-4} g/L at 20ºC (limit of quantification) at pH 7.7

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method
As the notified chemical is not soluble in volatile solvents at a concentration suitable for the column elution method, the flask method was used. Quantitative analysis was conducted using a spectrophotometric method developed and validated for the test substance.
TEST FACILITY Notox B.V. (2006e)

Hydrolysis as a Function of pH Not performed

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.
Remarks Since the water solubility of the test substance was below the quantification limit of the analytical method, the hydrolysis study could not be performed.
TEST FACILITY Notox B.V. (2006f)

Partition Coefficient (n-octanol/water) log Pow at 20ºC = 4.5 – 4.7

METHOD OECD 107 Partition Coefficient (n-octanol/water): Shake Flask Method

OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks: Analytical Method: HPLC. The test substance eluted between the reference substances 1,2,4-trichlorobenzene and fluoranthene, with three peaks observed.

TEST FACILITY: Notox B.V. (2006g)

Adsorption/Desorption log K_{oc} = 4.95 at 35°C (pH = 6).

METHOD: OECD 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography
EC Directive 2001/59/EC C.19 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography

Remarks: The notified chemical eluted between the reference substances phenantrene and 2,4-DDT.

TEST FACILITY: Notox B.V. (2006h)

Dissociation Constant Not performed

Remarks: The test substance was not tested. The notified chemical does not contain structural elements that are capable of dissociation.

Particle Size

METHOD: CTL SOP No. 417 (internal test guideline)
The test substance was initially observed to determine whether sieving of the material is required. The final sample was then analysed using the Coulter Laser Diffraction Analyser fitted with a small volume module (due to the sampling being a dye). Three runs were conducted to ensure repeatability of results. The test was conducted to BS ISO 13320-1:1999.

Range (μm)	*Mass (%)*
<0.868	10%
<2.109	25%
<10.63	50%
<26.81	75%
<43.45	90%

Remarks: Mass median aerodynamic diameter = approx. 49 μm (calculated according to the OECD Test Guideline 110: Particle Size Distribution/Fibre Length and Diameter Distributions).

TEST FACILITY: Chilworth Technology (2005)

Flash Point Not applicable

Remarks: The test substance is a low volatility solid.

Flammability Limits Not highly flammable

METHOD: EC Directive 92/69/EEC A.10 Flammability (Solids).
EC Directive 92/69/EEC A.12 Flammability (Contact with Water).

Remarks: The test substance could not be ignited and no propagation of combustion was observed. Therefore, the test substance is not highly flammable according to the criteria of the Directive.
On addition to water, no spontaneous ignition took place and no evolution of gas occurred. Therefore the test substance is incapable of developing a dangerous amount of flammable gases in contact with damp air or water.

TEST FACILITY: Notox B.V. (2006i)
Notox B.V. (2006j)

Autoignition Temperature >400°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The temperature of the test substance did not reach 400ºC before the oven temperature was 400ºC.
TEST FACILITY Notox B.V. (2006l)

Explosive Properties Not predicted to be explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The molecular structure of the notified chemical does not contain any chemically unstable or highly energetic groups that might lead to an explosion.

The oxygen balance for the test substance was calculated to be -175ºC. However, there are no bond groupings known to confer explosive properties or explosive enhancing groups present in the structure.

Overall consideration of the properties does not suggest a risk of explodability for the test substance.
TEST FACILITY Notox B.V. (2006m)

Pyrophoric Properties Not pyrophoric

METHOD EC Directive 92/69/EEC A.13 Pyrophoric Properties of Solids and Liquids.
Remarks Based on the molecular structures of the test substance and on experience in handling, it is not pyrophoric.
TEST FACILITY Notox B.V. (2006m)

Oxidising Properties Not oxidizing

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks Based on the composition of the test substance and the molecular structures of all three components in which one is the notified chemical, it was concluded that the test substance has no oxidizing properties.
TEST FACILITY Notox B.V. (2006n)

Reactivity Stable under normal conditions of use

Remarks No incompatible substances have been identified with the test substance. Conditions have not been identified which would contribute to the instability of the test substance and it is considered to be stable under normal conditions of use. Typical decomposition products are oxides of carbon, oxides of nitrogen and hydrogen chloride. No other toxic gases/vapours have been identified.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

All tests below were conducted using the imported product IRGAZIN® DPP Cosmoray Orange.

B.1. Acute toxicity – oral

TEST SUBSTANCE	IRGAZIN® DPP Cosmoray Orange
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar strain Crl:WI
Vehicle	20% Ethyl acetate in propylene glycol
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 F	2000	0
II	3 F	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	Hunched posture, piloerection, red faeces and red staining of several body parts were noted among animals between days 1 and 3. Breathing rales were recorded in one animal at the last observation time point on day 1.
Effects in Organs	No abnormalities observed.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Notox B.V. (2006o)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	IRGAZIN® DPP Cosmoray Orange
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Wistar strain Crl:WI
Vehicle	20% Ethyl acetate in propylene glycol
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	No abnormalities observed.
Signs of Toxicity - Systemic	Red staining of skin on several body parts, scales and/or scabs were seen on the treated skin of the animals during the observation period. These effects disappeared by Day 14 in the majority of the test animals, with the exception of 3 of the animals (2 males, 1 female).
Effects in Organs	No abnormalities observed.

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

TEST FACILITY Notox B.V. (2006p)

B.3. Irritation – skin

TEST SUBSTANCE IRGAZIN® DPP Cosmoray Orange

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 (Albino, SPF quality)
Number of Animals	3 males
Vehicle	Ethanol solution (50%)
Observation Period	72 h
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

No skin irritation was observed in any of the animals during the observation period. Orange staining of the treated skin was observed throughout the observation period, hampering the assessment of erythema at the 1 and 24 hr observation times.

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

TEST FACILITY Notox B.V. (2006q)

B.4. Irritation – eye

TEST SUBSTANCE IRGAZIN® DPP Cosmoray Orange

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 (Albino)
Number of Animals	3 males
Observation Period	72 hr
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	0.33	0.33	1	2	72 hr	0
Conjunctiva: chemosis	0	0	0	1	24 hr	0
Conjunctiva: discharge	0	0.33	0.33	1	48 hr	0
Corneal opacity	0	0	0	0	NA	0
Iridial inflammation	0	0	0	0	NA	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
NA = not applicable

Remarks - Results The test substance caused irritation of the conjunctivae, consisting of redness, chemosis and discharge. The irritation had completely resolved within 48 hours in two animals, and 72 hours in one animal. Remnants of the test substance were present in the eye on day 1 in two animals, and on day 1 and 2 in one animal. Red staining of the fur on the head and paws was noted during the observation period.

	No systemic toxicity or clinical symptoms were observed during the study.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Notox B.V. (2006r)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	IRGAZIN® DPP Cosmoray Orange
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay EC Directive 67/548/EEC B.42 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/CBA strain
Vehicle	Acetone/Olive oil (4:1 v/v)
Remarks - Method	No significant protocol deviations.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/animal)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	130 ± 51	1.0
5	173 ± 71	1.3 ± 0.5
10	206 ± 44	1.6 ± 0.4
25	191 ± 88	1.5 ± 0.6
*Positive Control** *(α-hexylcinnamicaldehyde, 85%)*		
0	262 ± 31	1.0
5	551 ± 173	2.1 ± 0.7
10	952 ± 226	3.6 ± 0.6
25	1969 ± 236	7.5 ± 0.4

* Based on data from regular reliability checks

Remarks - Results	Red staining was observed at all epidermally treated skin sites. Red discolouration of faeces was observed in animals treated with 10 and 25% of the test substance. The majority of nodes were normal in size, with the exception of one control animal, in which they were considered to be small, and one animal treated with 25% test substance in which the left node was considered to be slightly enlarged. Slight body weight loss was noted in some animals but was not considered to be toxicologically significant.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	Notox B.V. (2006s)

B.6. Repeat dose toxicity

TEST SUBSTANCE	IRGAZIN® DPP Cosmoray Orange
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 Crl:(WI) BR

Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	20% (w/w) Ethyl acetate in propylene glycol
Remarks - Method	No significant protocol deviations. Dosage levels were chosen based on a dose range-finding study.

RESULTS

Dose mg/kg bw/day	*Number and Sex of Animals*	*Mortality*
0	5 M, 5 F	0
50	5 M, 5 F	0
150	5 M, 5 F	0
1000	5 M, 5 F	0
0 (recovery)	5 M, 5 F	0
1000 (recovery)	5 M, 5 F	0

Clinical Observations

Red discoloration of faeces was observed in all animals treated with 50 mg/kg during week 4, and in all animals treated with 150 and 1000 mg/kg from week 1 onwards, and had resolved at the end of recovery. Red staining of fur was observed in a number of animals treated with 1000 mg/kg. This was considered to be related to exposure to the test substance and had disappeared at the end of recovery. These findings were considered toxicologically irrelevant.

In males treated with 1000 mg/kg, observations included alopecia in several body parts, scabs and wounds (periorbital region and the neck) and salivation in some animals. In females at the same dose level, scabs on the neck were observed. Such effects were observed at similar levels in control animals. In addition, the effects are commonly noted in rats of the age and strain and under the treatment conditions used in this study. As such, they were considered to be of no toxicological significance.

No significant changes were observed in body weight, food consumption or functional observations.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical chemistry

In males treated with 1000 mg/kg/day, statistically significant decreases in urea and creatinine levels were observed at the end of the treatment period. These were considered to be dose-related responses.

Levels of inorganic phosphate were observed to have decreased in a statistically significant fashion to the same level in males treated with 50 and 150 mg/kg/day (that is, the 50 and 150 mg/kg/day groups had identical levels of inorganic phosphate). As the decrease was not dose-related, it was not considered to be of toxicological significance.

Males treated with 150 and 1000 mg/kg/day were observed to have the same total bilirubin levels, which was a statistically significant reduction compared to the control animals. This was not considered to be dose related and hence was not of toxicological relevance.

In females treated with 150 mg/kg/day, a statistically significant increase in alanine aminotransferase was observed. As this was not a dose-related response, it was not considered to be of toxicological relevance.

In females at 1000 mg/kg/day, a slight but statistically significant increase in potassium level was found at the end of recovery. Based on the magnitude of the effect, the absence of this effect at the end of treatment and the variation within the group this finding was considered to be toxicologically irrelevant.

Haematology

There were no biologically relevant differences in haematological parameters in treated rats.

Effects in Organs

Reddish contents of the gastrointestinal tract were considered to be related to the test substance colour, but to

be of no toxicological importance.

There were no statistically significant changes in macroscopic findings in treated animals compared to the control animals. The following observations were made in a small number of animals (generally 1 animal from each treatment group): pelvic dilation and foci in kidneys, foci in epididymides, smaller seminal vesicles, enlarged spleen, red discoloration of the thymus, diaphragmatic hernia of the liver and cysts and fluid in the uterus. In addition, 3 males treated with 1000 mg/kg were observed to have enlarged mandibular lymph nodes, though this was not statistically significant. Such findings are occasionally seen among rats used in these types of studies. In the absence of correlated microscopic findings these were considered changes of no toxicological significance.

Statistically significant changes in relative kidney weights of males dosed at 150 mg/kg/day were considered to be of no toxicological importance based on the magnitude of the effect, absence of similar effects in animals treated at 1000 mg/kg/day and absence of corroborative macroscopic and microscopic findings.

There were no microscopic changes observed that could be attributed to treatment with the test substance. All findings were within the expected range for rats of this type and occurred at similar levels in control and treated rats.

Remarks – Results

No changes in clinical appearance, performance of functional observations, body weight and food consumption measurements, or alterations in the haematology investigation, macroscopic examination, organ weight determination and microscopic examination that were considered to be an effect of treatment. Isolated treatment-related changes were observed in clinical chemistry investigations, with decreased levels of urea and creatinine in male animals treated with 1000 mg/kg/day of the test substance.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 150 mg/kg bw/day in male animals based on isolated treatment-related clinical chemistry changes. The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the absence of any treatment related adverse effects at this dosage level.

TEST FACILITY Notox B.V. (2006t)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE	IRGAZIN® DPP Cosmoray Orange
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Rat liver S9 mix induced by a combination of phenobarbital and β-naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 1, 3, 10, 33, 100 µg/plate b) Without metabolic activation: 1, 3, 10, 33, 100 µg/plate
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	No significant protocol deviations. The positive control used for the assay performed without metabolic activation with TA100 was methyl methanesulfonate, which is not recommended by the OECD/EC test guideline.
RESULTS	
	Precipitation on the plates was observed at the start and end of the incubation period at concentrations of 100 µg/plate and upward. Some reductions in the bacterial background lawn of TA1537 were observed in the preliminary experiment in the absence of metabolic

activation. In the main experiment, a reduction in the bacterial background lawn of TA1535 was observed at the highest tested concentration in the absence of metabolic activation.
No increase in the number of revertants was observed upon treatment with the test substance.

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

TEST FACILITY Notox B.V. (2005a)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE IRGAZIN® DPP Cosmoray Orange

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 Peripheral human lymphocytes
Metabolic Activation System Rat liver S9 mix induced by a combination of phenobarbital and β-naphthoflavone
Vehicle Dimethyl sulfoxide (DMSO)
Remarks - Method No significant protocol deviations.
A dose range finding test was performed to select appropriate dose levels for the main tests.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1*, 3*, 10*	3 hr	24 hr
Test 2	1*, 3*, 10, 33*	24 hr	24 hr
Test 3	1*, 3*, 10, 33*	48 hr	48 hr
Present			
Test 1	1*, 3*, 10*	3 hr	24 hr
Test 2	1*, 3*, 10*	3 hr	48 hr

*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	>10*	>10	≥10	Negative
Test 2	>33*	>33	≥10	Negative
Test 3	>33*	>33	≥10	Negative
Present				
Test 1	>10*	>10	≥10	Negative
Test 2	-	>10	≥10	Negative

*Highest doses tested in preliminary test

Remarks - Results In Test 1 in the absence of metabolic activation, a statistically significant increase in the number of cells with chromosome aberrations was observed at the lowest tested concentration only, when gaps were included. Since the type of aberrations observed were only breaks and gaps, the increase was not dose related, and the number of cells with chromosome aberrations was within historical control range data, the increase was not considered to be biologically relevant.

CONCLUSION	The notified chemical was not clastogenic to peripheral human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	Notox B.V. (2006u)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: IRGAZIN® DPP Cosmoray Orange

METHOD: OECD TG 301 B Ready Biodegradability: CO2 Evolution Test.
EC Directive 92/69/EEC C.4-C Biodegradation: Determination of the " Ready" Biodegradability: Carbon Dioxide Evolution Test

Inoculum	Activated sludge
Exposure Period	28 days
Remarks - Method	No significant protocol deviations. Since the test substance was not sufficiently soluble to allow preparation of an aqueous solution at a concentration of 1 g/L, weighed amounts were added to the test bottles containing medium with microbial organisms and mineral components. The test solutions were continuously stirred during the test, to ensure optimal contact between the test substance and the test organisms. Since all criteria for acceptability were met, the study was considered to be valid.

RESULTS

Test substance		*Sodium Acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
5	0	5	46
9	0	9	63
14	0	14	71
19	0	19	76
23	0	23	76
27	0	27	76

Remarks - Results: The relative degradation values calculated from the measurements performed during the test period revealed no significant degradation of the test substance. In the toxicity control, the test substance was found not to inhibit microbial activity.

CONCLUSION: The notified chemical cannot be classed as ready biodegradable.

TEST FACILITY: Notox B.V. (2005b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE: IRGAZIN® DPP Cosmoray Orange

METHOD: OECD TG 203 Fish, Acute Toxicity Test - Static.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish- Static.

Species	Carp (*Cyprinus carpio*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	UV/Vis
Remarks – Method	Preparation of test solutions started with an aqueous mixture of 100 mg/L applying 1 day of magnetic stirring to reach maximum solubility. Subsequently, the mixture was left to stabilise for 1 day where after the

Water Accommodated Fraction (WAF) was siphoned. The final test solution was clear and slightly orange.

With an exception for the analytical results, due to the low water solubility level of the test substance, the study met the acceptability criteria prescribed by the protocol and was considered valid.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*4 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	7	0	0	0	0	0
100	<0.499	7	0	0	0	0	0

LC50	>100 mg/L (WAF) at 96 hours.
NOEC	100 mg/L (WAF) at 96 hours.
Remarks – Results	The LC50 was beyond a loading rate of 100 mg/L, i.e. beyond the maximum solubility in test medium (<0.499 mg/L)

CONCLUSION The notified chemical was not found to be harmful to Carp (*Cyprinus carpio*) up to the limit of its solubility in water.

TEST FACILITY Notox B.V. (2006v)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE IRGAZIN® DPP Cosmoray Orange

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	250 mg $CaCO_3$/L
Analytical Monitoring	UV/Vis
Remarks - Method	Preparation of test solutions started with an aqueous mixture of 100 mg/L applying 1 day of magnetic stirring to reach maximum solubility. Subsequently, the mixture was left to stabilise for 1 day where after the Water Accommodated Fraction (WAF) was siphoned. The final test solution was clear and slightly orange. The study met the acceptability criteria prescribed by the protocol and was considered valid.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	20	0	1
100	<0.499	20	0	1

LC50	>100 mg/L (WAF) at 48 hours
NOEC	100 mg/L (WAF) at 48 hours
Remarks - Results	After 48 hours, 5% of the daphnids exposed to the WAF and in the control were immobilised. Since 10% immobility is acceptable for the control, the effect observed in this test was not considered to be significant. No precipitation of test substance was observed during the test period.

The EC50 was beyond a loading rate of 100 mg/L, i.e. beyond the maximum solubility in test medium (<0.499 mg/L).

CONCLUSION The notified chemical was not found to be harmful to *Daphnia magna* up to the limit of its solubility in water.

TEST FACILITY Notox B.V. (2006w)

C.2.3. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE IRGAZIN® DPP Cosmoray Orange

METHOD OECD TG 211 Daphnia sp. Reproduction Test – Semi-Static.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia.

Species	*Daphnia magna*
Exposure Period	21 days
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	UV/Vis
Remarks - Method	Preparation of test solutions started with an aqueous mixture of 100 mg/L applying 1 day of magnetic stirring to reach maximum solubility. Subsequently, the mixture was left to stabilise for 1 day where after the Water Accommodated Fraction (WAF) was siphoned. The final test solution was clear and slightly red. The study met the acceptability criteria prescribed by the protocol and was considered valid.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*14 d*	*21 d*
0	0	20	1	3
100	<0.499	20	0	1

LC50	>100 mg/L (WAF) at 21 days
NOEC	100 mg/L (WAF) at 21 days
Remarks - Results	Three of the twenty parental daphnids exposed to the control died during the test period. Hence, parental mortality did not exceed 20% in the control group. Only one parental daphnid exposed to the WAF died during the test period. Hence, parental mortality in the WAF was insignificant. In the controls, the presence of eggs in the brood pouch was recorded for the first time on days 6-7 and in 88% of the surviving parents the first brood appeared on days 8-9. 58% of the surviving parents exposed to the WAF prepared at a loading rate of 100 mg/L had their first brood on day 9. During the exposure period, the test solutions were renewed three times a week. From day 13 onwards, test substance particles were observed in the test solutions, indicating that the daphnids were exposed to a concentration exceeding the water solubility limit.

CONCLUSION The notified chemical was not found to be harmful to *Daphnia magna* up to the limit of its solubility in water.

TEST FACILITY Notox B.V. (2006x)

C.2.4. Algal growth inhibition test

TEST SUBSTANCE	IRGAZIN® DPP Cosmoray Orange
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range Nominal	0, 100 mg/L (WAF)
Concentration Range Actual	0, <0.499 mg/L (WAF)
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	UV/Vis
Remarks - Method	Preparation of test solutions started with an aqueous mixture of 100 mg/L applying 1 day of magnetic stirring to reach maximum solubility. Subsequently, the mixture was filtered through a membrane filter to remove the major fraction of undissolved test substance particles (>0.45 µm). The final test solution was clear and colourless. No significant protocol deviations. The study met the acceptability criteria prescribed by the protocol and was considered valid.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOE_bC mg/L*	*E_rC50 mg/L at 72 h*	*NOE_rC mg/L*
>0.499 (WAF)	0.499 (WAF)	>0.499 (WAF)	0.499 (WAF)

Remarks - Results	The EC50 was beyond a loading rate of 100 mg/L, i.e. beyond the maximum solubility in test medium (<0.499 mg/L).
CONCLUSION	The notified chemical is very slightly toxic to *Selenastrum capricornutum*.
TEST FACILITY	Notox B.V. (2006y)

C.2.5. Inhibition of microbial activity

TEST SUBSTANCE	IRGAZIN® DPP Cosmoray Orange
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.
Inoculum	Municipal sewage treatment plant: 'Waterschap de Maaskant'
Exposure Period	0.5 hours
Concentration Range Nominal	0, 100 mg/L
Remarks – Method	No significant protocol deviations.
RESULTS	
IC50	>100 mg/L
NOEC	100 mg/L
Remarks – Results	The test substance was not toxic to waste water (activated sludge) bacteria at a concentration of 100 mg/L.

CONCLUSION	The notified chemical is very slightly toxic to the respiration rate of activated sludge.
TEST FACILITY	Notox B.V. (2005c)

BIBLIOGRAPHY

Chilworth Technology (2005), Particle Size Analysis (Study Number 449191), Southampton, United Kingdom. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Ciba Specialty Chemicals, Inc (2005a), Analytical Procedure (Study Number CEWB0097.LC), Basle, Switzerland. (Unpublished report provided by notifier)

Ciba Specialty Chemicals, Inc (2005b), Analytical Procedure (Study Number CEWB0053.GC), Basle, Switzerland. (Unpublished report provided by notifier).

Ciba Specialty Chemicals, Inc (2005c), Certificate of Analysis (Study Number 40056FC5), Basle, Switzerland. (Unpublished report provided by notifier).

European Commission (2003) Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market – Part I. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities.

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) Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:1003(1995)], National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

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

Notox B.V. (2005a), Evaluation of the Mutagenic Activity in the Salmonella Typhimurium Reverse Mutation Assay and the Escherichia Coli Reverse Mutation Assay (with Independent Repeat) (Study Number 449281), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2005b), Determination of Ready Biodegradability: Carbon Dioxide (CO_2) Evolution Test (Modified Sturm Test) (Study Number 449303), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2005c), Activated Sludge Respiration Inhibition Test (Contact Time: 30 minutes) (Study Number 449347), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006a), Development and Validation of an Analytical Method for the Analysis in Mill-Q Water (Study Number 449358), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006b), Determination of the Melting and Boiling Temperature by Differential Scanning (Study Number 449077), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006c), Determination of the Density (Study Number 449088), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier.)

Notox B.V. (2006d), Determination of the Vapour Pressure by the Static Method (Study Number 449099), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006e), Determination of the Water Solubility (Study Number 449112), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006f), Statement on the Determination of the Hydrolysis as a Function of pH (Study Number 449213), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006g), Determination of the Partition Coefficient (N-Octanol/Water) (Study Number 449213), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006h), Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC) (Study Number 449202), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006i), Determination of the Flammability (Study Number 449134), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006j), Statement on the Flammability (Contact with Water) (Study Number 449145), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006k), Determination of the Relative Self-Ignition Temperature (Study Number 449178), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006l), Statement on the Explosive Properties (Study Number 449167), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006m), Statement on the Pyrophoric Properties (Study Number 449156), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006n), Statement on the Oxidizing Properties (Study Number 449189), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006o), Assessment of Acute Oral Toxicity in the Rat (Acute Toxic Class Method) (Study Number 449224), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006p), Assessment of Acute Dermal Toxicity in the Rat (Study Number 449235), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006q), Primary Skin Irritation/Corrosion Study in the Rabbit (4-Hour Semi-Occlusive Application) (Study Number 449246), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006r), Acute Eye Irritation/Corrosion Study in the Rabbit (Study Number 449257), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006s), Assessment of Contact Hypersensitivity in the Mouse (Local Lymph Node Assay) (Study Number 449268), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006t), Repeated Dose 28-day Oral Toxicity Study by Daily Gavage in the Rat, Followed by a 14-Day Recovery Period (Study Number 449279), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006u), Evaluation of the ability to Induce Chromosome Aberrations in Cultured Peripheral Human Lymphocytes (with Repeat Experiment) (Study Number 449292), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006v), 96-Hour Acute Toxicity Study in Carp (Static) (Study Number 449314), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006w), Acute Toxicity Study in *Daphnia Magna* (Study Number 449325), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006x), Reproduction Test with *Daphnia Magna* (Semi-Static) (Study Number 473671), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).

Notox B.V. (2006y), Fresh Water Algal Growth Inhibition Test (Study Number 449336), Hertogenbosch, The Netherlands. Sponsor: Ciba Specialty Chemicals Inc., Basel, Switzerland (Unpublished report provided by notifier).