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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

**Tin, dichloro[29H,31H-phthalocyaninato(2-)-κN29,κN30,κN31,κN32]-, (OC-6-12)-
(Dichlorotin phthalocyanine)**

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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(Dichlorotin phthalocyanine)****1. APPLICANT AND NOTIFICATION DETAILS****APPLICANT(S)**

Itochu Australia LTD (ABN 63 000 192 790)
Level 8, 63 Exhibition Street
Melbourne VIC 3000

NOTIFICATION CATEGORY

Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Spectral data

Purity

Non-hazardous impurities

Introduction volume

Details of specific use

Identity of Manufacturer/Recipients

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Adsorption/Desorption

Dissociation constant

Hydrolysis as a function of pH

Flash point

Explosive properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

US EPA TSCA PMN (2005)

EU (UK HSE) (2005)

Korea (2006)

2. IDENTITY OF CHEMICAL**CHEMICAL NAME**

Tin, dichloro[29H,31H-phthalocyaninato(2-)-κN29,κN30,κN31,κN32]-, (OC-6-12)-

OTHER NAME(S)

29H,31H-Phthalocyanine, tin complex

Tin, dichloro[29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32]-, (OC-6-12)-

Tin, dichloro[phthalocyaninato(2-)]-(7Cl, 8Cl)

Dichlorotin phthalocyanine

MARKETING NAME(S)

Sanyo S-50 Phthalocyanine (imported mixture containing the notified chemical)

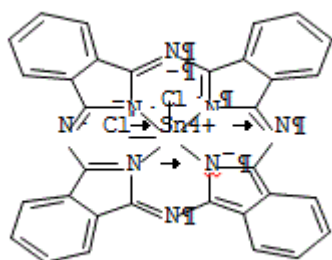
CAS NUMBER

18253-54-8

MOLECULAR FORMULA

C₃₂ H₁₆ Cl₂ N₈ Sn

STRUCTURAL FORMULA



MOLECULAR WEIGHT

702.15

ANALYTICAL DATA

Reference NMR, IR, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

>40%

4. PHYSICAL AND CHEMICAL PROPERTIES for the marketed product mixture

Appearance at 20°C and 101.3 kPa Blue powder

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 180 °C (decomposes)	Measured
Boiling Point	Not possible to determine as it decomposes at 180 °C	Measured
Density	1930 kg/m ³ at 20°C	Measured
Vapour Pressure	2.1x10 ⁻⁵ kPa at 20°C	Measured
Water Solubility	< 1 × 10 ⁻³ g/L at 20.2 ± 0.7°C	Measured
Hydrolysis as a Function of pH	Not provided	Although the test substance contains ligands which may exchange for hydroxyl ligands in water, the test substance has low water solubility and there is no analytical method to allow measurement at these levels. Any conversion at least in part will be to the other component in the mixture.
Partition Coefficient (n-octanol/water)	log Pow > 1.6 at 20.2±0.7°C	Estimated (see appendix C)
Adsorption/Desorption	log K _{oc} = 1.40	Estimated (QSAR model)
Dissociation Constant	The notified chemical is expected to be ionised in the environmental pH range (4-9).	Estimated from structure. The test substance requires sulphuric acid for dissolution and an analytical technique is not available for the test substance in water.
Particle Size	Inhalable fraction (<100 µm): <50% Respirable fraction (<10 µm): 6.8% Median diameter: 150.4 µm	Measured

Flash Point	Not provided	Not required for solids with high melting point
Solid Flammability	Not highly flammable	Measured
Autoignition Temperature	Not self-ignitable	Measured
Explosive Properties	Not expected to be explosive	Estimated

Discussion of Observed Effects

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

Reactivity

Notifier has advised that the experience in use and during the tests conducted indicated that this substance did not react or spontaneously ignite in contact with air or water. Additionally, consideration of the chemical structure shows no likely sites for hydrolytic or oxidative attack.

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 as a component (<50%) of a powder mixture.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	≤1	≤1	≤1	≤1	≤1

PORT OF ENTRY

Melbourne airport and port

TRANSPORTATION AND PACKAGING

The notified chemical will be imported packaged in 10 kg triple layer paper bags (inner layer is polypropylene film) and transported by road to the formulation site.

USE

Component of paints for use in OEM automotive industry

OPERATION DESCRIPTION

The notified chemical will not be manufactured in Australia, but will be imported as a component (<50%) of a mixture in 10 kg bags.

At the formulation site the imported mixture containing the notified chemical is formulated into paint. It is weighed into mixing vessels along with resins and solvents. The remainder of the formulation process takes place in closed vessels, with automated filling of the end product into packaging drums. The paint formulation is a batch process and the concentration of the notified chemical in the formulated paint is <0.5%.

At the end user sites the paint containing the notified chemical is used in the automotive industry, for original equipment manufacture (OEM). At the customer sites the paint will be stirred and diluted, then placed in a spray apparatus. The object to be painted will be sprayed then heat cured, resulting in the painted article.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Transportation and Storage	3	2-3 hours/day	10-15 days/year

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

Paint manufacture	3	30 min to 6 hrs/day	16 days/year
Quality control	4-8	1 hr/day	16 days/year
Cleaning operations	2	30 min/day	4 days/week
Paint application	3	8 hrs/day	50 days/year

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.

Paint formulation

During paint formulation, inhalation exposure to the notified chemical is possible for the workers during weighing of the raw powdered material. The particle size distribution of the raw material containing <50% of the notified chemical indicates that less than 50% of the particles are inhalable (< 100 µm) and 6.8% are respirable (< 10 µm). Exposure to the notified chemical in powder form is expected to be minimised by the use of personal protective equipment (PPE) such as safety glasses, protective clothing, gloves and a particle filter mask (during weighing and mixing) or a dust mask (during cleaning). Local exhaust ventilation in the weighing and loading areas, as well as at the mixers will also help minimize inhalation exposure. After this process, all operations are performed in the closed system and direct inhalation exposure is not expected.

Dermal and ocular exposure of workers to a maximum of 50% of the notified chemical is also possible during paint formulation during weighing of the imported material, charging of the mixing tank, taking QC testing samples and when plant and equipment is cleaned or maintained. Engineering controls such as metered dosing and enclosed mixing tanks will be in place to minimise dermal/ocular exposure. Personal protective equipment (PPE) will also be available and will be worn by workers during this process – coveralls, goggles, face shields and impermeable nitrile gloves. Respiratory protection is expected where dust generation occurs.

Workers involved in filling of cans of formulated paint may have dermal/ocular exposure to a maximum of 0.5% of the notified chemical. Workers will wear coveralls, goggles and impervious gloves.

Inhalation exposure during the later stages of formulation or during filling of paint is unlikely as aerosols are not expected to be formed and exhaust ventilation systems are in place to control exposure to other components in the paints.

End-use of paints in spray painting

Workers involved in spray application of the formulated paints in OEM plants may potentially have dermal ocular and inhalation exposure to the notified chemical during preparation and spraying of the formulated paint coatings to surfaces of the automotive parts and, during cleaning equipment after use. Exposure to workers at different sites where the paint will be used may vary, as variations are possible in the scale and sophistication of the spray-painting operations and the controls in place at each site. However, exposure is expected to be minimized through controls such as automated application systems, well ventilated work place, down draft spray booth with an effective fume extraction system and PPE equipment such as anti-static footwear and flame retardant overalls, impervious gloves, eye protection and an air fed breathing mask or respirator if local exhaust is inadequate. In addition, the low concentration of the notified chemical in the paint (<0.5%) will further reduce the potential for exposure.

6.1.2. Public exposure

Public exposure to the notified chemical is not expected, as it will be used in an industrial setting. The public may have contact with articles coated with paint containing the notified chemical. However, the chemical will be bound within the cured coating and will not be bioavailable.

6.2. Human health effects assessment

The results from toxicological investigations conducted on a mixture containing <50% of the notified chemical are summarised in the table below. Details of these studies can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	oral LD50 >2000 mg/kg bw low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	limited evidence of sensitisation
Genotoxicity – bacterial reverse	The results indicate that the test substance could elicit sensitisation non mutagenic

Based on tests in rats the notified chemical has low acute toxicity via oral route.

The notified chemical is not irritating to skin. Even though discoloration of the skin was observed for all the duration of the skin irritation study with rabbits, it was not significant as to mask evaluation of any eventual skin reactions. The notified chemical is slightly irritating to eyes. Based on the results of the skin and eye irritation studies, the notified chemical is not classified as a skin or eye irritant.

The notified chemical is considered to have skin sensitising potential as dermal application of 5 and 25% of the tested material in mice caused more than three times increase of lymphocyte proliferation. EC3 value could not be calculated from this study as no clear dose response was observed at the highest concentration. However, based on the positive results after treatment with 5% and 25% of the tested material, the notified chemical is classified as skin sensitiser.

The notified chemical was not found to be mutagenic to *E. coli* or *S. typhimurium* and cannot be classified as mutagenic.

Based on the results of the toxicological studies the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

R43 – May cause sensitisation by skin contact

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Dermal and ocular exposure is possible for workers involved in different steps of the paint formulation process (< 50% of the notified chemical) and also for workers involved in spray painting at the end-users sites (<0.5% of the notified chemical). Considering that the notified chemical is slightly irritating to the eye and may cause discoloration of the skin, there is a low risk of adverse local effects to the eyes and skin if exposure occurs. However, exposure is expected to be minimized by the presence of engineering controls such as metered dosing and enclosed mixing tanks for workers involved in the paint formulation process and the use of automated application systems, well ventilated work place, down draft spray booth with fume extraction system, in the case of the spray paint application workers. In addition, personal protective equipment (PPE) such as coveralls, goggles, face shields and impermeable nitrile gloves are also expected to be used by workers during the paint formulation and spray painting processes to minimize exposure.

The notified chemical is also a potential skin sensitiser. Considering the likelihood for dermal exposure of the workers involved in the paint formulation and paint application, the risk of skin sensitisation for workers cannot be excluded. However the risk for the paint application workers is minimal as the maximum concentration of the notified chemical to which these workers may be exposed is <0.5% and they are expected to use the PPE and engineering controls described above. The workers involved in paint formulation are likely to be exposed to higher concentrations of the notified chemical (50%), however their exposure is also expected to be minimized by the presence of engineering controls and PPE described above.

Inhalation exposure to particles of the raw material containing the notified chemical at <50% is likely for the workers involved in paint formulation as they will be handling, measuring and mixing the powdered material. The particle size distribution of the raw material indicates that less than 50% of the particles are inhalable (< 100 µm) and 6.8% are respirable (< 10 µm). No data is available on the systemic effects of the notified chemical or the potential for respiratory sensitisation. However, due to the significant percentage of inhalable particles in the raw material,

adverse effects associated with exposure to nuisance dust are possible. The risk of such effects will be minimized by the use of particle filter mask (during weighing and mixing) or a dust mask (during cleaning). In addition local exhaust ventilation in the weighing and loading areas, as well as at the mixers should be used to help minimize inhalation exposure. After this process, all operations are performed in the closed system and direct exposure is not expected. Inhalation exposure through generation of aerosols during end use is possible, but is expected to be minimized by the controls in place and the low concentration of the notified chemical in the paint.

Exposure through ingestion is not expected for any category of the workers.

Once formulation has occurred exposure to particulate raw material containing the notified chemical is not expected, and so the risk to workers involved in packaging, quality analysis and application of the paint is considered to be low.

Overall the risk to workers is considered to be low in the presence of the controls described.

6.3.2. Public health

The risk to public health is expected to be negligible as the exposure of public to the notified chemical is not expected except as part of cured coatings, where it will not be bioavailable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Due to the limited information available on the release and use of the chemical, a default scenario for reformulation and use of automotive paint products has been used.

As the notified chemical will be manufactured overseas there will be no release in Australia due to its manufacture. Until it reaches the coating manufacturing site, release to the environment during shipping, transport and warehousing will only occur through accidental spills where the packaging is breached.

Coating Formulation

The notified chemical will undergo reformulation, where it is blended with other ingredients to form an automobile surface coating, and will be stored in 200 L steel drums. At the coating manufacturing site, the annual release of the notified chemical will be via the following points:

Spills	- less than 1%, (< 10 kg per annum), to landfill
Import packaging	- less than 0.1%, (< 1 kg per annum), to licensed waste - contractor for landfill or incineration.
Equipment cleaning	- up to 1%, (< 10 kg per annum) to licensed waste - contractor for landfill or incineration.

During the coating formulation operations, it is anticipated that there will be minimal release of the notified chemical during manual transfer from the packaging to the mixers and during filling of coating into containers or during blending since it is undertaken in enclosed systems. Liquid spills of the formulated product will be within bunded areas and collected with inert absorbent material (eg sand) and placed in a sealable container ready for disposal. All generated washing effluent from the process equipment, including blending tanks and mixers, is likely to be sent to a licensed waste contractor for disposal by landfill or incineration.

RELEASE OF CHEMICAL FROM USE

Due to limited information available on the release and use of the chemical, a default scenario for spray painting components of new cars has been used.

The notified chemical as a component of an automotive coating will be sprayed onto components of new cars. It is expected that this will be done by robots with high transfer efficiency ($\geq 80\%$), with possible

manual touch up.

Annual release of the notified chemical to the environment as a result of its use in the automotive industry will include:

Spills	- less than 1%, up to 10 kg per annum, to landfill
Container residue	- less than 1%, up to 10 kg per annum, to waste contractor
Overspray and Equipment cleaning	- approx 20%, up to 200 kg per annum

All spills will be contained, collected with inert absorbent material (eg sand) and placed in a sealable container ready for disposal. All overspray will be contained, collected and allowed to harden ready for disposal. Application equipment will generally be cleaned with solvent. This effluent will be collected and allowed to harden before disposal.

Any coating residue in empty coating containers will be allowed to dry and then disposed of with the container to a licensed drum recycler.

RELEASE OF CHEMICAL FROM DISPOSAL

Any spilt material will be disposed of to landfill in sealed labelled containers.

Import and coating containers will be disposed of via a licensed drum recycler offsite, who will either incinerate any residues present or send them to landfill.

Any resultant overspray and cleaning effluent from coating application will be allowed to harden and will then be disposed of to landfill along with any spilt material.

7.1.2 Environmental fate

No environmental fate data for the notified chemical were provided. Refer to appendix "C" for the EU risk assessment report provided by the applicant on an analogue.

7.1.3 Predicted Environmental Concentration (PEC)

The notified chemical will be reformulated into coatings that will be used in automated systems or by specialist technicians in the OEM automotive industry, i.e. will not be available for general consumer use. The proposed use pattern and waste management indicate that solid wastes (containing up to 250 kg annually of the notified chemical) resulting from the coating will be collected and sent to landfill or incineration. A small amount of the notified chemical may be present in the final effluent from the effluent treatment plant, which will be either returned to the sludge tank or released to sewer.

The notified chemical will interact with other coating components to form a stable chemical matrix and, once dry, is expected to be immobile and pose little risk to the environment. After the useful life of the coated article, the notified chemical will share the same fate as the article. The articles are likely to be landfilled or enter metal recycling. If the article is recycled then the notified chemical will be thermally destroyed to release oxides of carbon and nitrogen; simpler chlorine compounds; water vapour and tin oxide.

7.2. Environmental effects assessment

No ecotoxicity data for the notified chemical were submitted. The results from the EU risk assessment for an analogue is summarised below. No test reports were supplied. Refer to Appendix C.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	EC50 > 100 mg/L	Practically non - toxic

Summary of environmental effects, referring to Appendix C for ecotox results.

7.2.1 Predicted No-Effect Concentration

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
		µg/L
Assessment Factor	1000	
Mitigation Factor	1.00	
PNEC:		≥ 100

A test result from the EU risk assessment for an analogue for one trophic level was available. Therefore an assessment factor of 1000 was applied and a PNEC of ≥ 100 µg/L was calculated.

7.3. Environmental risk assessment

A predicted environmental concentration (PEC) cannot be calculated on the reported use pattern. However, the chemical is expected to be mainly disposed of to landfill as waste or in cured paint product. Most will enter metal recycling and is expected to be thermally destroyed during this process. Aquatic exposure is therefore expected to be minimal. The PEC is expected to be considerably below the PNEC.

Based on the reported use pattern the risk to the environment is expected to be acceptable.

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 classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R43 – May cause sensitisation by skin contact

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.

	<i>Hazard category</i>	<i>Hazard statement</i>
Skin sensitisation	1	May cause allergic skin reaction

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.

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 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 should be in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC:2003).

10. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
 - R43 – May cause sensitisation by skin contact
- Use the following risk phrases for products/mixtures containing the notified chemical:
 - conc \geq 1% R43
- The following safety phrases should appear on the MSDS and label for the notified chemical:
 - S25: Avoid contact with eyes
 - S36 Wear suitable protective clothing
 - S37 Wear suitable gloves
 - S51: Use only in well-ventilated areas

Health Surveillance

- As the notified chemical is a potential skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation.

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
 - The level of atmospheric nuisance dust should be maintained as low as possible. The NOHSC exposure standard for atmospheric dust is 10 mg/m³.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
 - Avoid contact with eyes
 - Avoid generating and inhaling dusts
 - Clean-up operations should employ methods which avoid dust generation such as vacuuming (with appropriate filter) or wet clean-up
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
 - Chemical-resistant gloves
 - Safety eye protection
 - Protective clothing
 - Respiratory protection during processes where exposure to dust is likely

Guidance in selection of personal protective equipment can be obtained from

Australian, Australian/New Zealand or other approved standards.

- Spray painting with products containing the notified chemical should be carried out using engineering controls, safe work practices and PPE appropriate for OEM environment
- 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

Disposal

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

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical collection such as sweeping. Care should be taken as the powder is combustible. The collected material should be used to the extent practicable or placed into containers for disposal.

11. REGULATORY OBLIGATIONS

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of 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 must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the importation volume exceeds one tonne per annum notified chemical;
- or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from component of paints for use in OEM automotive industry, or is likely to change 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.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

All physico-chemical studies have been done on the marketed mixture containing the notified chemical.

Melting Point/Freezing Point >180°C

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	DSC method. Decomposition was observed to start at about 180 C. No melting of the test substance was noted prior to the onset of decomposition.
TEST FACILITY	NOTOX (2005a)

Boiling Point > 180°C at 101.3 kPa

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Decomposition was observed to start at about 180 C. No boiling was noted prior to the onset of decomposition.
TEST FACILITY	NOTOX (2005a)

Density 1930 kg/m³ at 20°C

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Test using gas comparison pycnometer
TEST FACILITY	NOTOX (2005b)

Vapour Pressure 2.1x10⁻⁵ kPa at 20°C

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	The vapour pressures was measured at the three test temperatures were all between 5x10 ⁻² and 5x10 ⁻¹ Pa. According to the OECD guideline the recommended range for the static method is 10 up to 10 ⁵ Pa. However, when using a capacitance manometer the static method can be used below 10 ⁻¹ Pa. This study was performed using a capacitance manometer with a measurement range 5x10 ⁻³ and 5x10 ⁵ Pa
TEST FACILITY	NOTOX (2005c)

Water Solubility < 1 × 10⁻³ g/L at 20°C

METHOD	In accordance with OECD TG 105 Water Solubility and EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method. Although results of a preliminary study indicated that the column elution method was the most suitable to determine the water solubility, it was not possible to prepare a suitable column, and the flask method had to be used. However, since the developed analytical method required concentrated sulphuric acid to fully dissolve the S-50 phthalocyanine, the matrix of the samples and the calibration solutions in the water solubility test could not be made identical, and measured concentrations were indicative at best. Solubility was therefore estimated by visual inspection and spectrophotometry. Test solutions were protected from light to the extent practicable during the test.
TEST FACILITY	NOTOX (2005d)

Partition Coefficient (n-octanol/water) Log Pow >1.6 at 20.2±0.7°C

Remarks	Neither a column elution nor flask method was considered technically feasible; it
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was not possible to pass the substance through an HPLC column, and the water solubility was below the limit of detection. Solubility in n-octanol was determined as 44 mg/L and then compared with the separately determined water solubility. However, since the developed analytical method required concentrated sulphuric acid to fully dissolve the S-50 phthalocyanine, the matrix of the samples and the calibration solutions in the n-octanol solubility test could not be made identical, and measured concentrations were indicative at best.

TEST FACILITY NOTOX (2005e)

Particle Size

METHOD BS ISO 13320-1:1999. Initially a visual analysis was conducted by microscope followed by Laser Diffraction Particle Size analogous to OECD TG 110.

<i>Range (μm)</i>	<i>Mass (%)</i>
≤ 10.00	6.8
< 17.09	10
< 58.12	25
< 150.4	50
< 287.9	75
< 463.8	90

Remarks The sample was observed to consist of single crystalline particles.

TEST FACILITY Chilworth (2005)

Flammability

Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).

Remarks In contact with the flame the test substance could be ignited. The test substance burned with a yellow sparks. After removal of the ignition source no more sparks were observed.

The substance is not "highly flammable" according to the criteria as described in the method guideline.

TEST FACILITY NOTOX (2005f)

Autoignition Temperature

Not self-ignitable

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

Remarks After the experiment the colour of the test substance has changed from dark blue to light greyish indicating decomposition.

The substance is "not self-ignitable" when tested up to 400°C according to the criteria as described in the method guideline.

TEST FACILITY NOTOX (2005g)

Explosive Properties

Not expected to be explosive

Remarks The notifier has used oxygen balance calculation and structural grounds to predict a lack of explosively in relation to the notified chemical, with the oxygen balance of the major component of the mixture calculated at -227.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Marketed mixture containing the notified chemical at <50%
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 67/548/EEC Annex V B.1 tris (2004) Acute Oral Toxicity
Species/Strain	Rat/Wistar CRI:WI (outbred SPF quality) female
Vehicle	Polyethylene glycol 400
Remarks - Method	No significant deviations from the protocol were reported.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3 female	2000	0
2	3 female	2000	0

LD50	>2000 mg/kg bw (considered to be > 5000 mg/kg bw under the decision tree of OECD TG 423)
Signs of Toxicity	No significant signs of toxicity were reported and the body weight gain over the study period was considered normal.
Effects in Organs	No abnormalities were reported at macroscopic level post mortem.
Remarks - Results	Hunched posture was noted in all animals on day 1. Blue staining of the anus region, faeces, back, shoulder and tail was noted among animals (no number or study day specified) during the study period.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
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TEST FACILITY	NOTOX (2005h)
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B.2. Irritation – skin

TEST SUBSTANCE	Marketed mixture containing the notified chemical at <50%
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 67/548/EEC B.4 Acute Toxicity Dermal Irritation/Corrosion.
Species/Strain	Albino Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	Water was used to moisten the test material
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant deviations from the protocol were reported. The test material was removed from the skin after 4 h with water and 50% ethanol.
Remarks - Results	Blue staining of the treated skin by the test substance was observed in all animals throughout the study period. However, no histopathology was performed, as the discoloration of the skin was appeared not to be significant as to mask the any skin reactions. In addition no systemic effects were reported after dosing with the material containing the notified chemical.

CONCLUSION	The notified chemical is non-irritating to the skin.
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TEST FACILITY NOTOX (2005i)

B.3. Irritation – eye

TEST SUBSTANCE Marketed mixture containing the notified chemical at <50%

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 67/548/EEC B.4 Acute Toxicity Eye Irritation/Corrosion.
Species/Strain Albino Rabbit/New Zealand White
Number of Animals 3 Male
Observation Period 7 days
Remarks - Method No significant deviations forms the protocol were reported.

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0.3 3	1.6 7	0.6 7	2	72 h	0
<i>Conjunctiva: chemosis</i>	0	0.6 7	0	2	48 h	0
<i>Conjunctiva: discharge</i>	0.3 3	0.6 7	0	1	48 h	0
<i>Corneal opacity</i>	0	0	0	0	-	0
<i>Iridial inflammation</i>	0	0	0	0	-	0

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

Remarks - Results No corneal or epithelial damage was detected upon fluorescein testing 24h post-treatment. Remnants of the test substance were present in the eye of one animal on day 1 and in another animal between days 1 and 3. Remnants were noted on the outside of the eyelids of one animal on day. However no staining of the eye was reported. Blue staining of the fur on the head and paws caused by the test substance was noted during the observation period.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY NOTOX (2005j)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Marketed mixture containing the notified chemical at <50%

METHOD OECD, Section 4, Health Effects No.429 (2002)
EC Directive 67/548/EEC annex V, B42 (2004)
Species/Strain Mouse/ CBA strain, inbred, SPF-quality, Female
Vehicle PEG 400
Remarks - Method Concentrations for testing were determined based on a preliminary irritation study using 1%, 2.5%, 5%, 10%, 25%, 50 % and 100% of test substance.
Results from two reliability studies using 14 and 12-week-old animals and the positive control alpha-hexylcinnamic aldehyde (HCA) in acetone/olive oil vehicle were presented. SI for the 25% solution of the positive control varied in these studies between 4.6 and 7.1 with EC3 varying from 9.5 to 17.0. Historical results for EC3 value for HCA in

acetone/olive oil in the lab vary from 2-20%.

RESULTS

<i>Concentration (% w/w)</i>	<i>Proliferative response (DPM/lymph node)</i>	<i>Stimulation Index (SI) (Test/Control Ratio)</i>
<i>Test Substance</i>		
0	225 ± 50	-
5	875 ± 575	3.6 ± 0.7
25	1244 ± 727	5.5 ± 0.6
50	277 ± 155	1.2 ± 0.6
<i>Positive Control alpha-hexylcinnamic aldehyde (HCA)</i>		
25	4670 ± 2677	18.5 ± 0.7

Remarks - Results

No irritation was observed at any concentration in the preliminary study. No scoring of erythema was possible due to green/blue staining by the test substance. No oedema was observed in any of the animals. Body weights were normal. Enlarged lymph nodes were observed in one animal of the 25% test group. Other animal in the same test group had reduced lymph nodes. The stimulation indices did not show a dose response pattern, with the lowest SI occurring at the highest test concentration.

CONCLUSION

There was inadequate evidence of induction of a lymphocyte proliferative response. The results indicate that the test substance could elicit an SI ≥ 3 (i.e. skin sensitisation). However no reliable EC 3 value could be calculated. Therefore, there is limited evidence of sensitisation.

TEST FACILITY

NOTOX (2005k)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE

Marketed mixture containing the notified chemical at <50%

METHOD

OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.

Species/Strain

Plate incorporation procedure/Pre incubation procedure

S. typhimurium:

TA1535, TA1537, TA98, TA100

E. coli: WP2 uvrA

Metabolic Activation System

Aroclor 1254 induced rat liver S9 fraction

Concentration Range in

a) With metabolic activation: 1-5000 µg/plate.

Main Test

b) Without metabolic activation: 1-5000 µg/plate.

Vehicle

DMSO (solution at ≥ 100 mg/L, suspension at higher concentrations)

Remarks - Method

Adequate positive controls were used.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	Not observed	Not observed	≥ 100	no
Test 2	-	Not observed	≥ 100	no

<i>Present</i>				
Test 1	Not observed	Not observed	≥ 100	no
Test 2		Not observed	≥ 100	no

Remarks - Results

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

TEST FACILITY NOTOX (20051)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

ENVIRONMENTAL FATE

C.1.1. Ready biodegradability

Not tested

Remarks - Results 1 % degradation was reported in the EU risk assessment provided by the notifier for a Japanese MITI test on an analogue copper phthalocyanine (EU Notification).

CONCLUSION It is unlikely that the phthalocyanine component of the analogue or notified chemical will be readily biodegradable. No test reports were provided.

ECOTOXICOLOGICAL INVESTIGATIONS

C.2.1. Acute toxicity to fish

Not tested. The EU risk assessment provided by the notifier reported a 48 hour LC50 > 100 mg/L (*Oryzias latipes*) for an analogue copper phthalocyanine. The notified chemical has low water solubility and is therefore unlikely to dissolve in the aquatic environment at levels toxic to aquatic species.

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