File No: STD/1330

July 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Sicopal 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, Water, Heritage and the Arts.

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

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN 62 008 437 867)
500 Princes Highway, Noble Park, VIC 3174

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, CAS number, Molecular formula, Structural formula, Molecular weight, Spectral data, Methods of detection and determination, Degree of purity, Impurities, Import volume, Use details and identity of recipients

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Hydrolysis as a function of pH, Partition co-efficient, Adsorption/Desorption, Dissociation constant, Flash point, Explosive properties, Acute dermal toxicity, Chromosome damage, Ready biodegradation, Bioaccumulation

NOTIFICATION IN OTHER COUNTRIES
Europe, Canada

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sicopal Orange L 2430, Sicopal Orange K 2430

OTHER NAME(S)
Tin titanium zinc oxide
Tin transition metals oxide

MOLECULAR WEIGHT
300-600 Da

ANALYTICAL DATA
Reference IR, UV/VIS, X-ray Fluorescence Spectrometry, XRD diffractogram and Differential Scanning Calorimetry spectra were provided (BASF 2007a, BASF 2007b and BASF 2008a).

3. COMPOSITION

DEGREE OF PURITY > 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Orange powder

Property	Value	Data Source/Justification
Melting Point	> 590°C	Measured
Boiling Point	Not determined	-
Density	4941 kg/m^3 at 20°C	Measured

Vapour Pressure	$< 10^{-7}$ kPa at 20°C	Measured
Water Solubility	$< 5 \times 10^{-4}$ g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	Very low water solubility.
Partition Coefficient (n-octanol/water)	Not determined	Very low solubility in water and n-octanol.
Adsorption/Desorption	Not determined	Very low water solubility.
Dissociation Constant	Not determined	Water Solubility is $< 5 \times 10^{-4}$ g/L at 20°C. The chemical does not contain any functional groups that are expected to dissociate in water.
Particle Size	Inhalable fraction (< 100 μm): 100% Respirable fraction (< 10 μm): 97.32%	Measured
Flammability (solids)	The substance is not considered to be highly flammable.	Measured
Flammability (contact with water)	The substance is not considered to be highly flammable.	Measured
Autoignition Temperature	No self heating was detected.	Measured
Explosive Properties	Not determined	Based on the chemical structure, the result for the explosive properties has been predicted to be negative.
Oxidising Properties	Not considered an oxidising substance	Measured

DISCUSSION OF PROPERTIES

As noted above, several physico-chemical properties could not be determined because of the very low water solubility of this inorganic pigment. The notified chemical is expected to be stable to hydrolysis, immobile in soils, and to have a low potential for bioaccumulation because of very low solubility in octanol. For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity

The notified chemical is stable at normal conditions.

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 of Sicopal Orange (> 90%) via ship in 25 kg packs.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-3	3-10	10-30	10-30	10-30

PORT OF ENTRY

Sydney or Melbourne

IDENTITY OF RECIPIENTS

BASF Australia Ltd
500 Princes Highway, Noble Park, VIC 3174

TRANSPORTATION AND PACKAGING

Sicopal Orange containing the notified chemical (> 90%) will be imported into Australia via ship in 25kg packs. From the wharf, it will be transported by road (truck) to a contracted third party warehouse (in Melbourne or Sydney). It will be distributed from these premises by road to a number of customers.

USE

The notified chemical is used as a colouring agent for the plastics (< 3%) and coatings industries (< 10%).

OPERATION DESCRIPTION
Sicopal Orange containing the notified chemical (> 90%) will be imported and transported directly to the contracted warehouse for storage until required for delivery to customers. At the customer's facility, store persons will receive and transfer drums of the notified chemical by forklift to various work areas as required, for example, warehouse or production areas.

Various techniques would be employed to incorporate the notified chemical into plastics and coating formulations. Specifically, in the plastics application, batch preparation would require a manual weighing-up process, then dispersion into extruders with other ingredients. The notified chemical may be firstly incorporated into masterbatches at a concentration of 5-50% prior to further processing. Plastics applications would result in the manufacture of moulded articles.

Similarly in the coatings application, batch preparation would require a manual weighing-up process followed by dispersion into bead or sand mills. Resulting coating formulations would be packed into containers for sale.

Products would be tested by QC technicians. Pallets of packed products will be stored and sold to customers for use in a variety of industrial and domestic applications. Around 50% of the introduced volume will be used in industrial plastics and 50% in liquid coatings.

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*
Transport and Warehouse	2-4	2 hours/day	20 days per year
Plant Operators – Weighing and Compounding	4-6	8 hours / day	48 days per year
Plant Operators – Filling and Packaging	2-4	2 hours / day	48 days per year
Laboratory/Quality Assurance Technicians	1-2	1 hours / day	48 days per year
Drum Recyclers	1	0.5 hours / day	48 days per year
Professional Tradesmen	1000	8 hours / day	200 days per year

EXPOSURE DETAILS
Transport and warehouse workers are unlikely to be exposed to the notified chemical except in case of handling damaged drums. Should this occur, workers are expected to wear suitable personal protective equipment (PPE) and contain and collect the spill using absorbent material for recovery or disposal.

Coatings manufacture
Inhalation of airborne particles of the notified chemical is expected to be the main route of potential exposure during manual weighing and transfer into the hopper and addition to mixers. The MSDS supplied by the notifier recommends the use of respiratory PPE with a particle filter during handling of powdered notified chemical.

Once the notified chemical is no longer in powder form, minimal inhalation exposure is anticipated. Formation of aerosols during formulation and packing is not expected.

Dermal and ocular exposure is also possible from spills, drips and splashes during the blending of the notified chemical with other coating components and during product sampling and filling. The exposure will be reduced by expected automated processes. Process workers handling the notified chemical are also expected to wear PPE such as chemical-resistant gloves and safety glasses with side shields to minimise exposure.

Plastics manufacture
Inhalation exposure to airborne particles of the notified chemical could occur during manual weighing and transfer into blending vessels and extruders. Inhalation exposure is expected to be similar to that described above for coatings manufacture. However, it is anticipated that local exhaust ventilation (LEV) will be in use and workers at particular risk will wear respirators to minimise inhalation exposure. In addition, the notifier states that other PPE including safety glasses with side shields and chemical-resistant gloves should be used to

minimise any accidental dermal and ocular exposure.

Once incorporated into the finished moulded plastic article or masterbatch, no further exposure is anticipated as the notified chemical will be incorporated in the solid plastic.

Drum recyclers
Drum recyclers will be exposed to the notified chemical via inhalation, dermal and ocular routes when collecting empty import drums. LEV and PPE, including a suitable respirator is expected to be in use to minimise inhalation exposure.

Professional use of coating products
Professional tradesmen will experience dermal and ocular exposure to coatings containing the notified chemical (< 10%) during spray, roller and brush application. However, exposure is expected to be minimised by the use of PPE during spray application such as safety glasses, gloves and coveralls. Application of coating products may also take place in a spray booth which would further minimise the potential for exposure.

After application and once dried, the coatings will be cured into an inert matrix and the notified chemical will be unavailable for exposure.

6.1.2. Public exposure
The potential for exposure of the public to the notified chemical during normal industrial storage, handling and transportation is negligible, except in the case of an accident.

Do-it-yourself (DIY) users could experience dermal, ocular and inhalation exposure to coatings containing < 10% notified chemical during spray, roller or brush applications in a similar way to tradesmen, however the frequency of exposure is expected to be less than professional tradesmen. DIY users are more likely to apply coatings by brush or rollers but spray applications may also occur. They are less likely to have access to engineering controls or to use PPE.

After application and once dried, the coating will be cured into an inert matrix and the notified chemical will not be available for exposure.

Once incorporated into the finished moulded plastic article, no further exposure is anticipated as the notified chemical will be incorporated in the solid plastic.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 > 5000 mg/kg bw, low toxicity
Rat, acute dermal toxicity	Not determined
Rat, acute inhalation toxicity	LC50 = 5.7 mg/L/4 hours, low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro <Mammalian Chromosome Aberration> Test	non genotoxic

Toxicokinetics, metabolism and distribution
The potential for absorption across biological membranes may be limited by the very low solubility in water (< 5 × 10^{-4} g/L). In oral toxicity studies the presence of an orange discolouration of the faeces suggests that a main route of excretion is via the faeces. Airborne dusts of the notified chemical will be easily inhaled given that 100% are within the inhalable size range and 97% the particles are respirable. Particles of inhalable size will deposit in the nose, throat and upper respiratory tract, and a large proportion is likely to be cleared by muco-ciliary action and orally ingested. Respirable particles that deposit in the lower respiratory tract cannot be cleared by mucous and ciliary mechanisms and may be retained deep in the lungs, with long-term inhalation possibly leading to particle accumulation.

Acute toxicity
The notified chemical is of low acute toxicity *via* the oral route. No acute dermal toxicity data are available. Although the notified chemical was concluded to have low toxicity via inhalation in an acute inhalation study as no mortality occurred in the treated animals, significant lesions were present in the lungs. These lesions consisted of congestion, intra-alveolar histocytosis with numerous pigment-loaded macrophages and multifocal interstitial lymphoplasmahistiocytic infiltrates, suggestive of a reaction process due to the inhalation of dust particles containing the notified chemical.

Irritation
Based on the in vitro and in vivo studies provided, the notified chemical is considered to be slightly irritating to eyes and skin.

Sensitisation
There was no evidence of skin sensitisation to the notified chemical in a local lymph node assay using mouse under the conditions of the test.

Repeated dose toxicity
The oral No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the absence of observed adverse effects at the highest dose level.

The effects after repeated inhalation exposure were not investigated. As respiratory effects were observed for several days after a single inhalation exposure, the potential exists for the chemical to cause adverse respiratory effects after repeated exposure.

Genotoxicity
Poor solubility was a limiting factor and doses were restricted to relatively low concentrations due to precipitation, particularly in the chromosome aberration test. The notified chemical did not cause significant cytotoxicity in bacterial and mammalian cells and was not mutagenic or clastogenic at the doses tested.

Toxicity of related chemicals: tin oxide, titanium oxide and zinc oxide
Acute exposure to tin oxide may result in mild irritation to the skin, eyes, and mucous membranes. Chronic exposure may result in benign pneumoconiosis that may be apparent in distinctive changes in progressive chest X-rays during the time of the exposure (OSHA 2009a).

Acute exposure to zinc oxide can result in coughing, substernal pain, upper respiratory tract irritation, rales, chills, fever, nausea, and vomiting. Chronic exposure to zinc oxide by skin contact may result in papular-pustular skin eruptions in the axilla, inner thigh, inner arm, scrotum and pubic areas (OSHA 2009b).

TiO_2 is a poorly soluble, low toxicity dust. NIOSH has determined that insufficient evidence exists to designate TiO_2 as a potential occupational carcinogen (NIOSH 2005).

Health 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).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified chemical contains a high proportion of inhalable and respirable particles that have the potential to cause adverse respiratory effects if airborne dusts are inhaled. No repeat dose inhalation study was conducted however given the high level of insoluble respirable particles, there is potential for accumulation in the lungs following repeated exposure. Dust exposure could also pose a greater health risk for individuals with pre-existing respiratory conditions such as asthma or allergies. Exposure is most likely to occur during manual weighing and transfer of the powder and workers are expected to be trained in low dust handling techniques and engineering controls in place to prevent dust generation, such as local exhaust ventilation, dust collectors or wet dust suppression systems. Workers that are directly exposed are expected to wear suitable respiratory protection as stated in the MSDS. Further, fine dust particles could land on the mucous membranes of the eyes and cause slight eye irritation, therefore eye protection is expected to be worn.

Safe Work Australia has recommended exposure standards for related chemicals: Time-Weighted Average (TWA) for tin oxide (2 mg/m^3), titanium dioxide (10 mg/m^3), zinc oxide (dust) (10 mg/m^3) and zinc oxide (fume) (5 mg/m^3), and Short Term Exposure Limit (STEL) for zinc oxide (fume) (10 mg/m^3). These values would be useful guideline if air monitoring of the notified chemical is performed.

The notified chemical is not expected to pose an inhalation risk when mixed with liquid components, but workers could experience dermal and eye exposure through splashes and spills, therefore PPE (gloves, coveralls and safety glasses) would reduce skin and eye contact during both formulation and end use of coatings.

Inhalation exposure to the notified polymer may occur during end use spray operations (at concentrations of less than 10%), particularly when used outdoors. Exposure is expected to be reduced by various control measures, including use of spray booth, engineering controls and PPE.

Workers may experience dermal exposure to moulded plastic articles or cured coatings containing the notified chemical. In this form the notified chemical is expected to be cured into an inert matrix and will not be available for exposure. Therefore the risk to workers from exposure to the notified polymer in articles and cured coatings is expected to be low.

Overall, the risk to workers during coatings and plastics manufacture is not unacceptable if the proposed engineering controls are in place and PPE is worn.

6.3.2. Public health

While the use of coatings containing the notified chemical (< 10%) by DIY users is expected to be considerably less frequent than professional tradesmen, the use of appropriate PPE is also thought to be less common, leading to potential for incidental dermal and ocular exposure during roller and brush applications. However, the extent of exposure and risk is not expected to be significant.

Application of coatings containing the notified chemical (< 10%) by spray is less likely with DIY users but presents a potential for inhalation exposure. Some risk of adverse respiratory effects following repeated inhalation exposure via spray application cannot be excluded unless appropriate respiratory protection is used.

The public may experience dermal exposure to moulded plastic articles or cured coatings containing the notified chemical. In this form the notified chemical is expected to be cured into an inert matrix and will not be available for exposure. Therefore the risk to the public from exposure to the notified polymer in articles and cured coatings is expected to be low.

Overall, coatings containing the notified chemical are not expected to present an unacceptable risk to the health of DIY users.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported into Australia at Melbourne or Sydney, and stored at a contracted warehouse experienced in handling chemical. It will be transported by road to various customers. Environmental exposure comes from two main routes. The first route of environmental exposure arises from accidental spills. The notified chemical should be contained physically, collected in an absorbent material, and disposed to secure landfill. The second route of environmental exposure arises from the disposal of import containers with residual notified chemical. It is expected that only trace quantities of imported notified chemical will remain in these containers, which will be sent to drum reconditioners. Emptied packaging will ideally follow lifecycle processes (e.g. cleaning and washing, reconditioning and re-use) but may instead be dumped or incinerated in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

The formulation of the notified chemical into coatings is not expected to generate significant quantities of waste as it is a simple blending process. Similarly, the inclusion of the notified chemical into plastic articles is a simple extrusion process. The notifier estimates that 0.01-0.5% of the notified chemical may require disposal as formulation wastes.

Injection moulded articles or paint for roof coatings/architectural coatings for building exteriors can be used in a wide variety of applications but due to the expected stability of the colour, no significant release of the product is expected during the use of the articles or coatings. Coatings may be applied by brush, roller or spray. Powder coatings may or may not be applied using electrostatic methods. The level of waste generated will vary, and may reach up to 40% for spray booth application.

RELEASE OF CHEMICAL FROM DISPOSAL

Disposal of all wastes created during the formulation process is the same as for emergency waste management, that is, incineration or disposal to controlled landfill following negotiation with the relevant authority. Waste from use as coatings is likely to be disposed of to landfill as solid waste. Plastic articles are likely to be disposed of to landfill at the end of their useful life.

7.1.2 Environmental fate

No environmental fate data were submitted. The notified chemical is an inorganic pigment with very low water solubility that is expected to remain associated with the coatings and plastic articles into which it is incorporated. If released from these matrices, it would be expected to partition to the solid phase (sludge, sediment or soil) where it will remain immobile. The notified chemical is not expected to contaminate water, or to bioconcentrate in fish.

7.1.3 Predicted Environmental Concentration (PEC)

It is neither necessary nor meaningful to determine a PEC as the notified chemical is not expected to contaminate water.

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	LL50 > 100 mg/L	Not toxic to limit of water solubility
Daphnia Toxicity	EL50 > 100 mg/L	Not toxic to limit of water solubility
Algal Toxicity	EL50 = 10-100 mg/L	Not toxic to limit of water solubility
Inhibition of Bacterial Respiration	EL50 > 1000 mg/L	Not harmful

Fish, daphnids and algae were exposed to water accommodated fractions, after filtration. Fish and daphnids were exposed to a single test concentration. The dose-response seen in algae appears to reflect a soluble zinc contaminant.

7.2.1 Predicted No-Effect Concentration (PNEC)

It is neither necessary nor meaningful to determine a PNEC as the exposure concentrations in the aquatic toxicity tests were not determined. The notified chemical is not toxic to aquatic life at concentrations up to the solubility limit.

7.3. Environmental risk assessment

The notified chemical is not considered to pose a risk to the environment, based on its properties and the reported use pattern. The notified chemical is not expected to enter aquatic environments, and is not toxic to aquatic life at concentrations up to the solubility limit.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical during manual weighing and powder transfer:
  - Local exhaust ventilation and/or appropriate dust extraction systems

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during manual weighing and transfer:
  - Use of low-dust handling techniques
  - Air monitoring if inhalation exposure is likely
  - Clean-up of any spills

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Eye protection
  - Gloves
  - Respiratory protection where the chemical is handled in powder form

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

- Spray application should be carried out in accordance with the National Guidance Material for Spray Painting.

- 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.

Public Health

- Coatings designed for spray application by the public should recommend use of respiratory protection.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
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 of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a colouring agent for plastics (up to 3%) and coatings (up to 10%), or is likely to change significantly;
- the amount of chemical being introduced has increased from 30 tonne per year, or is likely to increase, significantly;
- 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.

Material Safety Data Sheet
The MSDS of the products containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point > 590ºC

Method OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Differential Scanning Calorimetry method was used.
Test Facility BASF (2007c)

Density 4941 kg/m^3 at 20ºC

Method OECD TG 109 Density of Liquids and Solids.
Remarks Pycnometer method was used.
Test Facility BASF (2007c)

Vapour Pressure < 10^{-7} kPa at 20ºC
< 10^{-7} kPa at 50ºC

Method OECD TG 104 Vapour Pressure.
Remarks Effusion method (weight loss) was used.
Test Facility BASF (2007c)

Water Solubility < 5×10^{-4} g/L at 20ºC

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method was used. Solubility was determined by elemental analysis (inductively coupled plasma - mass spectrometry). The values obtained (< 0.3 mg/L for Sn, < 0.5 mg/L for Ti and up to 2.7 mg/L for Zn) indicate that the notified chemical contains a water soluble zinc contaminant.
Test Facility BASF (2007c)

Hydrolysis as a Function of pH

Method The test could not be conducted because of the very low water solubility of the test substance.

Partition Coefficient (n-octanol/water)

Method The test could not be conducted because of the very low water solubility of the test substance. Solubility in n-octanol was also very low (< 0.016 g/L).

Adsorption/Desorption

Method The test could not be conducted because of the very low water solubility of the test substance.

Particle Size 0.12-46 µm

Method In-house method

Particle size (µm)	*Mass (%)*
≤ 0.55	11.68
≤ 1.66	50.44
≤ 10	97.32
< 100	100

Remarks Laser diffraction method with evaluation according to Fraunhofer was used.
Test Facility BASF (2007c)

Flammability Limits (solids) The substance is not considered to be highly flammable.

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The preliminary test was negative. No burning time was measurable. The main test was omitted due to result of preliminary test.

Flammability Limits (contact with water) The substance is not considered to be highly flammable.

Method EC Directive 92/69/EEC A.12 Flammability (Contact with Water).
Test Facility BASF (2007b)

Autoignition Temperature No self heating was detected.

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Test Facility BASF (2007b)

Oxidizing Properties The test substance is not considered an oxidising substance.

Method EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks The maximum burning rate of the mixtures tested is lower than the burning rate of the reference mixture.
Some values of burning time deviated by more than 10% from the mean value for the given composition, which is above the value specified by the directive. However, as the highest burning rate of the test substance is clearly below the highest burning rate of the reference substance, the result is still unequivocal.
Test Facility BASF (2007b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 2004/73/EC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Crl:(WI)BR
Vehicle	Suspension in 0.5% aqueous solution of Na-carboxymethylcellulose
Remarks - Method	No significant deviation from the protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	1F	5000	0
2	2F	5000	0

LD50	> 5000 mg/kg bw
Signs of Toxicity	No toxic effects were noted during the observation period. An orange discolouration of the faeces was observed in all animals 1d after the administration. This finding was not considered to be a toxic effect.
Effects in Organs	All animals were normal at the necropsy 14 d after the administration.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Austrian Research Centers (2007)

B.2. Acute toxicity – inhalation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 403 Acute Inhalation Toxicity – Limit Test. EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation) – Limit Test.
Species/Strain	Rats/Wistar
Vehicle	None
Method of Exposure	Head-nose exposure
Exposure Period	4 hours
Physical Form	Dust
Particle Size	1.3 and 1.4 µm (mass median aerodynamic diameter)
Remarks - Method	No significant deviation from the protocol.

RESULTS

Group	*Number and Sex of Animals*	*Concentration <mg/L>*		*Mortality*
		Nominal	*Actual*	
1	5 per sex	104.3	5.7	0

LC50	> 5.7 mg/L/4 hours
Signs of Toxicity	Clinical signs of toxicity comprised visually increased respiration and

	squatting posture. Findings were observed from hour 1 of exposure through to study day 1. No clinical signs and findings were observed from study day 2 onward.
Effects in Organs	Diffuse red discolouration of the lung, moderate retraction of the lung tissues and moderate to severe interstitial oedema were noted in all animals at necropsy, 14 days after dosing. Histopathological examination of the lungs of one male and one female animal was carried out and revealed moderate to severe acute diffuse congestion, moderate to severe diffuse intra-alveolar histiocytosis with numerous pigment-loaded macrophages and multifocal interstitial lymphoplasmahistiocytic infiltrates, graded as minimal to slight in the male animal and moderate in the female animal. The lung of the examined female animal was more affected. In this female animal, emphysema, perivascular cuffing and interstitial fibrosis were also noted.
Remarks - Results	The main body weight of the male and female animals increased throughout the whole study period.
CONCLUSION	The notified chemical is of low toxicity via inhalation.
TEST FACILITY	BASF (2008b)

B.3. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	EpiDerm Corrosivity-Test in vitro (summary only was provided) Analogous to OECD TG 431: In Vitro Skin Corrosion: Human Skin Model Test
RESULTS	
Remarks - Results	Non-corrosive according to the protocols of the study
CONCLUSION	The notified chemical is non corrosive.
TEST FACILITY	BASF (2007d)

B.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (sex unknown)
Vehicle	Minimally moistened with a suitable amount of doubly distilled water
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant deviation from the protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0.3	1	< 48 h	0
Oedema	0	0	0	0	-	0

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

Remarks - Results: Moderate erythema (grade 2) was observed was observed in all animals immediately after removal of the patch and persisted in one animal up to 1 hour. Slight erythema (grade 1) was noted in two animals after 1 hour and in one animal at the 24-hour reading.

The cutaneous reactions were reversible in two animals within 24 hours and in one animal within 48 hours after removal of the patch.

CONCLUSION: The notified chemical is slightly irritating to the skin.

TEST FACILITY: BASF (2008c)

B.5. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD: HET-CAM (Hen's Egg Test Chorioallantoic Membrane) Test (summary only was provided)

RESULTS

Remarks - Results: In order to further assess the acute eye irritation potential of the test substance, an eye irritation test in rabbits was later performed according to the method described in OECD guideline 405.

CONCLUSION: The notified chemical did not produce changes indicative of serious eye damage.

TEST FACILITY: BASF (2007e)

B.6. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 (sex unknown)
Observation Period: 28 days
Remarks - Method: No significant deviation from the protocol.

RESULTS

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

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

Remarks - Results: Moderate conjunctival redness (grade 2) was observed in two animals 1 hour after application and persisted in one animal up to 24 hours. Moderate conjunctival redness decreased to slight (grade 1) after 24 hours or 48 hours in one animal, respectively. The third animal showed slight conjunctival redness after one hour, only. Slight discharge (grade 1) was

noted in two animals after one hour.

In addition injected scleral vessels in a circumscribed area were noted in the animals during the observation period. No further details were provided in the study, however, this comment is thought to refer to effects seen in 2 animals at 1 hour and one animal at 24 hours.

The ocular reactions were reversible within 72 hours in all animals.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY BASF (2008d)

B.7. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin sensitisation: mouse local lymph node assay.
Commission Directive 2004/73/EC B.42 Skin sensitisation: mouse local lymph node assay.

Species/Strain Female Mice/CBA/J

Vehicle Propylene glycol

Remarks - Method A pretest with a 50% test substance preparation showed slightly increased ear weights and lymph node weights which were considered indications of ear irritation. Therefore the 50% preparation was the maximum technically applicable concentration used in the main study.

The study considered changes in lymph node cell counts and increase in lymph node weights, as additional indicators of sensitisation, in addition to thymidine incorporation.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	254.3 ± 58.4	1.00
3%	250.6 ± 84.2	0.99
10%	301.5 ± 83.6	1.19
50%	525.7 ± 141.8	2.07
Positive Control (HCA, alpha-hexyl cinnamaldehyde)		
10% in acetone	1225.6 ± 453.5	4.82

Remarks - Results No signs of systemic toxicity were noticed. The stimulation index (SI) for increase in ^{3}H-thymidine incorporation into cells was less than 3, indicating that the notified chemical is not a sensitiser.

Lymph node weights showed some increase, but not in a dose-dependent manner. An increase in lymph node cell count slightly above the stimulation index of 1.5 (considered the threshold for biological relevance by the study authors) was noted in the 50% group but not at lower concentrations. As this result was borderline and was not accompanied by a dose-related increase, it was not considered significant.

The results obtained for the positive control substance demonstrated the activity of the test system.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative

response indicative of skin sensitisation to the notified chemical.

TEST FACILITY BASF (2008e)

B.8. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EEC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain	Rats/Crl:WI (Han)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: none
Vehicle	Drinking water with 1% carboxymethylcellulose
Remarks - Method	No significant deviation from the protocol.

RESULTS

Number and Sex of Animals	*Dose (mg/kg bw/day)*	*Mortality*
5 per sex	0	0
5 per sex	100	0
5 per sex	300	0
5 per sex	1000	0

Mortality
No animal died prematurely in the study.

Clinical Observations
Discoloured faeces (orange) was observed in all rats of both sexes of 300 mg/kg bw/day group. In addition, all animals of both sexes of 1000 mg/kg bw/day group showed red-discoloured faeces. These findings are expected to be related to the coloured nature of the test compound (solid, orange) and were not considered adverse. No substance-related significant changes were observed in food or water consumption or body weight, nor in the functional observational battery and motor activity measurement.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Minor changes in the relative neutrophil/lymphocyte counts, prothombin time and cholesterol values were not considered adverse. No other changes in haematology or clinical chemistry were noted. No treatment related changes were found in the urine.

Effects in Organs
Organ weights
In the 300 mg/kg bw/day dose group the adrenal glands showed a mild but significant decrease and the spleen a mild but significant increase in relative organ weight, in comparison to the control group. In the absence of histopathological changes or dose dependence, these changes are considered incidental. All other weight parameters were comparable to the controls.

Gross lesions
In the 1000 mg/kg bw/day dose group, the content of the caecum showed an orange discolouration without any associated histopathology. The colouration is attributed to the test substance itself and is not regarded as an adverse effect. All other gross lesions occurred singly or were biologically equally distributed between control and treatment groups.

Histopathology
All findings noted were either single observations or equally distributed between control and treatment group, and are considered to be incidental or spontaneous in origin and without any relation to treatment.

Remarks – Results

In clinical examinations, the notified chemical did not cause any signs of general systemic toxicity. In clinical pathology testing no substance-related or adverse effect was found. There were no adverse substance-related weight changes, gross lesions or microscopic findings in organs in male and female Wistar rats.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study.

TEST FACILITY BASF (2008f)

B.9. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure and Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Aroclor 1254-induced rat liver S9 mix
Concentration Range in Main Test	Standard plate test a) With metabolic activation: 0, 20, 100, 500, 2500, 5000 µg/plate b) Without metabolic activation: 0, 20, 100, 500, 2500, 5000 µg/plate Pre incubation test a) With metabolic activation: 0, 312.5, 625, 1250, 2500, 5000 µg/plate b) Without metabolic activation: 0, 312.5, 625, 1250, 2500, 5000 µg/plate
Vehicle	Dispersion in Dimethylsulfoxide
Remarks - Method	No preliminary test was carried out.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Standard plate test			
Present	> 2500	> 2500	negative
Absent	> 2500	> 2500	negative
Pre incubation test			
Present	> 2500	> 2500	negative
Absent	> 2500	> 2500	negative

Remarks - Results Weak bacteriotoxic effects were observed with some strains at highest concentrations in the per incubation studies only.

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

TEST FACILITY BASF (2007f)

B.10. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Species/Strain	Chinese hamster
Cell Type/Cell Line	V79 cell line
Metabolic Activation System	Aroclor 1254-induced rat liver S9 mix

Vehicle	Dispersion in Dimethylsulfoxide
Remarks - Method	In range-finding studies, the test substance exhibited clear toxicity after 4 hour exposure in the absence of S9 mix only. Precipitation was observed that interfered with the chromosome analysis down to low concentrations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Test 1			
Absent	0*, 0.5, 1.0*, 2.0*, 4.0*, 8.0	4 h	18 h
Present	0*, 0.5, 1.0*, 2.0*, 4.0*, 8.0	4 h	18 h
Test 2			
Absent	0*, 0.5, 1.0*, 2.0*, 4.0*, 8.0	18 h	28 h
Absent	0*, 2.0, 4.0*, 8.0	18 h	28 h
Present	0*, 0.5, 1.0*, 2.0*, 4.0*, 8.0	4 h	28 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Test 1			
Absent	> 8.0	≥ 8.0	negative
Present	> 8.0	≥ 8.0	negative
Test 2			
Absent	> 8.0	≥ 8.0	negative
Absent	> 8.0	≥ 8.0	negative
Present	> 8.0	≥ 8.0	negative

Remarks - Results

No suppression of the mitotic activity or growth inhibition was observed. Osmolarity and pH values were not influenced by test substance treatment.

Precipitation was the limiting factor for does selection for the evaluation of cytogenetic damage. At 8 µg/mL and above the precipitates interfered with the chromosome analysis.

No relevant increase in the number of cells containing numerical chromosomal aberrations was observed in the absence and the presence of metabolic activation.

The positive control substances clearly demonstrated the sensitivity of the test system and of the metabolic activity of the S9 mix employed.

CONCLUSION

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

TEST FACILITY

BASF (2008g)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

METHOD: The test was not conducted because the notified chemical is an inorganic pigment that can be regarded as not biodegradable.

C.1.2. Bioaccumulation

METHOD: The test could not be conducted because the notified chemical is an inorganic pigment with very low solubility in water and octanol, and would therefore not be expected to bioconcenbtrate in fish.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test - static.

Species	Zebrafish (*Danio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Analysis for dissolved zinc by inductively coupled plasma - optical emission spectrometry (ICP-OEM).
Remarks – Method	A limit test only was conducted at a nominal loading of 100 mg/L. The test substance was dispersed using a high shear mixer followed by stirring for 7 days. Test media were filtered (0.2 µm) before testing to remove undissolved material. The filtered solution was visibly clear and colourless.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	7	0	0	0	0	0
100	0.05	7	0	0	0	0	0

LL50	> 100 mg/L at 96 hours.
NOEL	100 mg/L at 96 hours.
Remarks – Results	Results are expressed as nominal loadings, before filtration. All fish remained normal with no symptoms of intoxication.

CONCLUSION: Not toxic to fish up to the limit of water solubility.

TEST FACILITY: BASF (2008h)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 202 Daphnia sp. Acute Immobilisation Test - static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None

Water Hardness	Not reported
Analytical Monitoring	Analysis for dissolved zinc by ICP-OEM.
Remarks - Method	A limit test only was conducted at a nominal loading of 100 mg/L. The test substance was dispersed by stirring for 7 days. Test media were filtered (0.2 µm) before testing to remove undissolved material. All test solutions were visibly clear and colourless over the exposure period.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	5	0	0
100	0.136	5	0	0

LL50	> 100 mg/L at 48 hours*]*
NOEL	100 mg/L at 48 hours
Remarks – Results	Results are expressed as nominal loadings, before filtration.

CONCLUSION Not toxic to daphnids up to the limit of water solubility.

TEST FACILITY BASF (2008i)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test

Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 0, 1, 10 and 100 mg/L Actual: 0.0045, 0.0085, 0.014 and 0.19 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Analysis for dissolved zinc by ICP-OEM.
Remarks - Method	The test substance was dispersed by stirring for 7 days. Test media were filtered (0.2 µm) before testing to remove undissolved material. The filtered solutions were visibly clear and colourless. EDTA was not included in the test medium.

RESULTS

Biomass		*Growth*	
E_bL50	*NOEL>*	*E_rC50*	*NOEL*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
10-100	10	10-100	10

Remarks - Results	Algal cell density increased by a factor of 28, satisfying the validity criterion. Results are expressed as nominal loadings, before filtration. Algae were more sensitive than usual to the reference substance (potassium dichromate) in the absence of EDTA. Algal cell density at 72 hours was reduced relative to controls at the highest test loading, but increased at lower test loadings. It appears that these effects were caused by dissolved zinc, from a soluble contaminant in the test substance.

CONCLUSION Not toxic to algae up to the limit of water solubility.

TEST FACILITY BASF (2008d)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 62.5, 125, 250, 500 and 1000 mg/L
Remarks – Method	
RESULTS	
IC50	> 1000 mg/L
Remarks – Results	Bacterial respiration (oxygen consumption) varied from controls by no more than 10%, with no clear dose response.
CONCLUSION	Not harmful to bacterial respiration.
TEST FACILITY	BASF (2007j)

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