File No.: STD/1708

February 2020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Tin titanium tungsten zinc oxide

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

This Public Report is 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:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, 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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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1708	IMCD Australia Limited	Tin titanium tungsten zinc oxide	No	≤ 50 tonnes per annum	Component of plastics and coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human Health Risk Assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental Risk Assessment
On the basis of the import volume and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical during reformulation:
  - Enclosed/automated processes if possible
  - Local exhaust ventilation and/or appropriate dust extraction systems

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation:
  - Avoid inhalation of dust

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during reformulation or end use:
  - Respiratory protection if inhalation exposure may occur

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

- A copy of the SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Emergency procedures

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

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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(1) of the Act; if
  - the final use concentration of the notified chemical in coatings for spray application exceeds 15% for DIY use;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of plastics and coatings, or is likely to change significantly;
  - the amount of chemical being introduced has increased, 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.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
IMCD Australia Limited (ABN: 44 000 005 578)
Level 1, 372 Wellington Road
MULGRAVE VIC 3070

NOTIFICATION CATEGORY
Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Similar to a chemical that has been previously assessed by NICNAS

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: other names, molecular weight, analytical data, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for hydrolysis as a function of pH, adsorption/desorption, dissociation constant, flash point, auto ignition temperature, explosive properties, oxidising properties, acute dermal toxicity, acute inhalation toxicity, repeated dose toxicity, chromosome damage *in vitro*, ready biodegradation, acute fish toxicity, acute Daphnia toxicity and acute algal toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU REACH (2017)
China (2010)
Korea (2013)
Philippines (2019)
Switzerland (2017)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sicopal® Red EH 2370 (product containing the notified chemical at > 90% concentration)

CHEMICAL NAME
Tin titanium tungsten zinc oxide

CAS NUMBER
1800376-54-8

MOLECULAR FORMULA
O.Sn.Ti.W.Zn

MOLECULAR WEIGHT
< 600 g/mol

ANALYTICAL DATA
Reference XRF, IR and UV-VIS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Orange-brown powder

Property	*Value*	*Data Source/Justification*
Melting Point	> 600 °C	Measured
Boiling Point	Not determined	Expected to be high based on high melting temperature
Density	5,470 kg/m^3 at 20 °C	Measured
Vapour Pressure	Not determined	Expected to be low based on high melting temperature
Water Solubility	< 0.011 g/L at 23 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains no hydrolysable functionalities
Partition Coefficient (n-octanol/water)	log Pow < -0.03 at 23 °C	Estimated from individually measured solubilities in water and in n-octanol
Adsorption/Desorption	Not determined	Expected to have low mobility in soil due to its low water solubility
Dissociation Constant	Not determined	Contains no dissociable functionalities
Particle Size	Mean by surface: 272 µm Mean by volume: 678 µm Inhalable fraction (< 100 µm): 9.85% Respirable fraction (< 10 µm): 0.00%	Measured
Flash Point	Not determined	The notified chemical is a solid
Flammability	Not flammable	Measured
Autoignition Temperature	Not determined	Based on the structure self-igniting is unlikely (SDS)
Explosive Properties	Not explosive	Measured
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES
For details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The notified chemical is expected to be stable under normal conditions of handling and storage.

Physical Hazard Classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

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 powder at > 90% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10	10	10	30	50

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The product containing the notified chemical at > 90% concentration will be imported into Australia via ship in 25 kg paper bags. Within Australia it will be transported to a warehouse for storage and later distributed to industrial customers by road.

USE
The notified chemical will be used as a colourant in plastics at < 5% concentration and coatings at ≤ 15% concentration.

OPERATION DESCRIPTION

Reformulation
For plastic applications the notified chemical will be manually weighed and added to a blending vessel for mixing with other components. The resulting powdered mixture will then be automatically transferred to a feed hopper of an extruder from which it will be melted and extruded into pellets containing the notified chemical at ≤ 50% concentration.

In coating applications, the notified chemical will be manually weighed and mixed at high speed with a dispersion binder and then passed through a bed or sand mill. Resulting coating formulations will be packed into containers for sale.

End Use
The finished coatings containing the notified chemical at ≤ 15% concentration will be used by professional workers and do-it-yourself (DIY) users and applied by roller, brush, or spray.

At the customer sites, the polymer masterbatch pellets containing the notified chemical at ≤ 50% concentration will be manually added to a hopper and mixed with polymers and other additives. The resulting mixture will then be melted and extruded or injection moulded into plastic articles. The finished plastics will contain the notified chemical at < 5% concentration.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Warehouse	1-2	10-30
Plant operators –Weighing and Compounding	8	40-50
Plant operators – Filling and Packaging	1-2	40-50
Laboratory/Quality Assurance Technicians	1	40-50
Painters	8	200

EXPOSURE DETAILS

Transport and warehouse
Transport and warehouse workers are not expected to be exposed to the notified chemical except in the unlikely event of an accidental rupture of packaging.

Reformulation
Dermal, ocular and inhalation exposure to the notified chemical in powdered form may occur during manual weighing and transfer into the mixers and hoppers, and during product sampling and packaging. The notifier states that dermal and ocular exposure is expected to be minimised through the anticipated automated processes and use of personal protective equipment (PPE) such as coveralls, impervious gloves and safety glasses. The notifier states that inhalation exposure is expected to be minimised by the use of local exhaust ventilation and respiratory protection during handling of the powder as required.

Once incorporated into plastic masterbatches or moulded into finished articles, the notified chemical is expected to be trapped within the polymer matrix and will not be available for exposure.

Professional end use of coating products
Professional tradesmen may experience inhalation, dermal and ocular exposure to coatings containing the notified chemical at ≤ 15% concentration during spray, roller and brush applications. The notifier states that the exposure is expected to be minimised through the use of PPE such as safety glasses, impervious gloves, coveralls and respiratory protection (during spray applications), and the use of engineering controls including spray booths when used in an industrial environment.

Once the coatings are cured and dried, the notified chemical is expected to be trapped within the coating matix and will not be available for exposure.

6.1.2. Public Exposure
The public may experience dermal, ocular and inhalation exposure to the notified chemical at ≤ 15% concentration during application of coatings containing it by spray, roller or brush. The frequency and scale of exposure is expected to be less than professional tradesmen and DIY users are more likely to apply coatings by brush or rollers, but spray applications may also occur. The public are less likely to use PPE.

Once the coatings are cured and dried, the notified chemical is expected to be trapped within the coating matix and will not be available for exposure.

The public may also come into contact with plastic articles containing the notified chemical. Once incorporated into finished plastic articles, the notified chemical is expected to be trapped within the polymer matrix and will not be available for exposure.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the notified chemical and an analogue chemical (STD/1330) are summarised in the following table. For details of the studies on the notified chemical, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Acute oral toxicity – rat	LD50 > 2000 mg/kg bw; low toxicity
Acute inhalation toxicity – rat	LC50 = 5.7 mg/L/4 hours; low toxicity*
Skin irritation – *in vitro* EpiDerm™	non-irritating (no classification required)
Eye irritation – *in vitro* EpiOcular™	non-irritating (no classification required)
Skin sensitisation – mouse local lymph node assay	no evidence of sensitisation at up to 25% concentration
Repeat dose oral toxicity – rat, 28 days	NOAEL= 1,000 mg/kg bw/day*
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* mammalian chromosome aberration test	non genotoxic*

*Analogue reported in STD/1330

Toxicokinetics
No toxicokinetic data of the notified chemical were submitted. Based on the low water solubility (< 0.011 g/L at 23 °C), the potential for absorption across biological membranes is expected to be limited.

Acute Toxicity
The notified chemical is of low acute oral toxicity based on a study conducted in rats. No acute dermal and acute inhalation toxicity data are available for the notified chemical.

An analogous chemical (STD/1330) was shown to have low toxicity in an acute inhalation study in rats with no mortality occurring in the treated animals, although 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. Although similar in chemical composition, the analogue chemical had a significantly smaller particle size with 97.32% in the respirable range < 10 μm, compared to no respirable particles in the notified chemical.

Irritation
According to the results of *in vitro* assays, the notified chemical is not classified as a skin and eye irritant. However, mild skin and eye irritation effects cannot be ruled out.

Sensitisation
There was no evidence of sensitisation to the notified chemical in a mouse local lymph node assay (LLNA) when tested at up to 25% concentration.

Repeated Dose Toxicity
No information was available on the effect of repeated exposure to the notified chemical. For an analogous chemical (STD/1330), the oral No Observed Adverse Effect Level (NOAEL) was established as 1,000 mg/kg bw/day in a 28 day study in rats, based on the absence of observed adverse effects at the highest dose level in the study.

Titanium dioxide may cause serious damage to health from repeated inhalation exposure, predominantly due to lung overloading and impaired lung clearance mechanisms (NICNAS).

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), zinc oxide (fume) (5 mg/m^3) and tungsten (insoluble compounds as W) (5 mg/m^3) (SWA, 2019). The Short Term Exposure Limit (STEL) for zinc oxide (fume) is 10 mg/m^3 and for tungsten (insoluble compounds as W) is 10 mg/m^3 (SWA, 2019).

Mutagenicity/Genotoxicity
The notified chemical was found to be not mutagenic in a bacterial reverse mutation study. An analogous chemical (STD/1330) showed no evidence of genotoxicity in an *in vitro* chromosomal aberration test in Chinese hamster V79 cells.

Health Hazard Classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation
Based on the available information, the notified chemical is expected to be of low systemic and local toxicity. However, analogous chemicals have been shown to cause adverse effects following inhalation of powdered material. The notified chemical will be introduced as a powder, but only contains a small amount of inhalable particles (9.85%) and no respirable particles; hence the potential for inhalation toxicity from exposure to dusts of the notified chemical is expected to be low, compared with the analogue chemical.

6.3.1. Occupational Health and Safety
Exposure to the notified chemical is most likely to occur during manual weighing and transfer of the neat powder as introduced for reformulation purposes or during application of coatings containing the notified chemical at ≤ 15% concentration. Exposure to the notified chemical is expected to be minimised by the use of local exhaust ventilation, spray booths, and PPE including respiratory protection during handling of the powder and spray application. Safe Work Australia has recommended exposure standards for related chemicals, and these values would be a useful guideline for air monitoring of the notified chemical if performed.

Provided that the proposed engineering controls are in place and PPE is worn by workers, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health
DIY users may be exposed to the notified chemical at ≤ 15% concentration during application of coatings containing the notified chemical by brush, roller or spray. The use of coatings containing the notified chemical by DIY users is expected to be less frequent than professional tradesmen. The notified chemical is expected to be of low toxicity with the exception of any potential adverse effects following inhalation of spray droplets. However, the notified chemical contains no respirable particles but contains ~10% inhalable particles. The inhalable particles will be trapped inside spray droplets, and with ≤ 15% concentration in spray products, the notified chemical is not expected to cause inhalation risks with infrequent use of low volumes by DIY users.

The public may experience dermal exposure to moulded plastic articles or cured coatings containing the notified chemical; however, the notified chemical is not expected to be available for exposure.

Therefore, when used in the proposed manner, the notified chemical is not considered to pose an unreasonable risk to public health.

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 as a powder at > 90% concentration and will be used as a colourant for plastics and coatings. As estimated by the notifier, up to 0.5% of the imported volume of the notified chemical may be lost during the formulation of the notified chemical into coatings and plastics. These formulation wastes are expected to be disposed of in accordance with local government regulations. Accidental spills of the notified chemical during import, transport, storage or formulation are expected to be collected for reuse or disposal to landfill, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

Plastics containing the notified chemical will be moulded into consumer articles mainly for outdoor applications, including playground equipment, rubbish bins and kayaks.

The finished coatings containing the notified chemical will be used by professional workers and DIY users and applied by rollers, brush, or spray. Waste from the professional application is expected to be disposed of by an approved waste contractor. Any spills and drips from DIY use are expected to be collected on a suitable absorbent material and disposed of in accordance with local government regulations. As a worst case scenario, it is assumed that ≤ 5% of coatings containing the notified chemical used by DIY users may be incorrectly disposed of into sewers, drains, or the ground from waste and washing of application equipment.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical will share the fate of the plastic or coating articles in which they have been incorporated. They may enter recycling streams, but they will ultimately end up in landfill at the end of their useful lives. Empty containers/bags containing residual notified chemical ideally follow lifecycle processes (e.g. cleaning and washing, reconditioning and re-use) but may instead be disposed of to landfill, in accordance with local government regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified chemical is expected to be ultimately disposed of to landfill at the end of their useful lives. In landfill, most of the notified chemical will be present as cured solids and will be neither bioavailable nor mobile. A small proportion of the coatings used by DIY users may be incorrectly disposed of into sewers, and is expected to be removed through adsorption to sludge at sewage treatment plants based on its low water solubility. Sludge containing the notified chemical may be sent to landfill for disposal or agricultural land for remediation. Based on its low water solubility, the notified chemical is expected to bind to soil or sludge and expected to have low mobility in the environment.

7.1.3. Predicted Environmental Concentration (PEC)

The use pattern will result in a portion of the notified chemical being washed into the sewer. The predicted environmental concentration (PEC) has been calculated assuming the realistic worst-case scenario with 5% release of the notified chemical into sewer systems nationwide over 365 days per annum. The extent to which the notified chemical is removed from the effluent in STP processes based on the properties of the notified chemical has not been considered for this scenario, and therefore no removal of the notified chemical during sewage treatment processes, is assumed. The PEC in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50,000	kg/year
Proportion expected to be released to sewer	5	%
Annual quantity of chemical released to sewer	2,500	kg/year
Days per year where release occurs	365	days/year

Daily chemical release:	6.85	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor – River	1	
Dilution Factor – Ocean	10	
PEC – River:	1.40	µg/L
PEC – Ocean:	0.14	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 1.40 µg/L may potentially result in a soil concentration of approximately 9.36 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 46.81 µg/kg and 93.63 µg/kg, respectively.

7.2. Environmental Effects Assessment

A transformation/dissolution test (OECD TG 29) shows leaching of zinc from the notified chemical. Zinc is an essential element, but may become toxic at high concentrations. In general organisms have evolved to regulate their internal concentration of zinc independent of the concentration in the surrounding environment, and the European Communities (2008) determined that dissolved zinc may become toxic when the environmental concentration increases by more than 7.8 µg/L above the background concentration, or 3.1 µg/L in soft water (total hardness < 24 mg/L as $CaCO_3$).

The ecotoxicity of the notified chemical is caused by leached zinc. Zinc and compounds relevant to the notified chemical are listed on Australian Inventory of Chemical Substances. Currently, in Australia, zinc and its relevant compounds are not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for acute and chronic toxicities. Therefore the notified chemical is similarly not classified.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has not been calculated for the notified chemical as it is not an appropriate calculation determining the effects of an essential element leached from the notified chemical.

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has not been calculated as the PNEC could not be determined. However, based on the PEC of the notified chemical (1.40 µg/L) the amount of additional zinc will not cause the concentration of soluble zinc to exceed 3.1 µg/L above background concentrations. Therefore based on the proposed import volume and use pattern, the notified chemical is not expected to be harmful to aquatic life. Accordingly, based on the import volume and assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point > 600 °C

Method OECD TG 102 Melting Point/Melting Range
EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature
Remarks Determined using differential scanning calorimetry (DSC)
Test Facility BASF (2016a)

Density 5,470 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids
EC Council Regulation No 440/2008 A.3 Relative Density
Remarks Gas pycnometer method was used.
Test Facility BASF (2016a)

Water Solubility < 0.011 g/L at 23 °C

Method OECD TG 105 Water Solubility
Remarks The notified chemical is a mixture of different components which contains different water soluble fractions. Flask Method was used (Column Elution Method was not feasible as the notified chemical was not soluble in appropriate solvents).
Test Facility BASF (2016b)

Partition Coefficient (n-octanol/water) log Pow < -0.03 at 23 °C

Method OECD TG 105 Water Solubility
Remarks Flask method. Estimated from individually measured solubilities in water and in n-octanol.
Test Facility BASF (2017a)

Particle Size Mean by surface: 272 µm; mean by volume: 678 µm

Method In-house method: laser diffraction method based on ISO 13320

Particle distribution

d(0.1) (µm)	d(0.5) (µm)	d(0.9) (µm)
101	610	1,363

Range (µm)	*Mass (volume %)*
< 4	0.00
< 10	0.00
< 100	9.85

Remarks Range measured: 0.02 – 2,000 µm
Test Facility BASF (2016a)

Flammability Not flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids)
Remarks Brief burning followed by rapid extinction was observed.
Test Facility BASF (2016c)

Explosive Properties Not explosive

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks DSC measured from 30 to 500 °C at 2.5 °C/min
Test Facility BASF (2016c)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/Crl:WI (Han) (outbred, SPF-Quality)
Vehicle	Suspension in 0.5% aqueous solution of CMC (sodium carboxymethylcellulose, Dow Wolff Cellulosics GmbH) in deionised water
Remarks – Method	GLP compliant No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	3F	2000	0/3
2	3F	2000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	No toxic effects were noted during the observation period. All animals made the expected body weight gains.
Effects in Organs	No macroscopic pathological findings were observed at necropsy
CONCLUSION	The notified chemical of low acute toxicity via the oral route.
TEST FACILITY	Bioassay (2016)

B.2. Skin Irritation – *In Vitro* EpiDerm™ Reconstructed Human Epidermis Model

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method EC Council Regulation No 440/2008 B.46 BIS. *In vitro* Skin Corrosion – Reconstructed Human Epidermis Test Method - EpiDerm™ Reconstructed Human Epidermis Model
Vehicle	Moistened with phosphate buffered saline
Remarks – Method	GLP compliant No significant protocol deviations

RESULTS

Test Material	*Mean OD_{570} of Triplicate Tissues*	*Relative Mean Viability (%)*	*SD of Relative Mean Viability*
Negative control	1.821	100	8.8
Test substance	1.703	93.5	12.7
Positive control	0.060	3.3	0.3

OD = optical density; SD = standard deviation

Remarks – Results	The test substance was shown not to directly reduce MTT. The relative mean tissue viability for the test substance as compared to the negative control was 93.5%. Given that the relative mean tissue viability for the test substance was > 50%, it is considered as a non-irritant.

	The positive and negative controls performed as expected.
CONCLUSION	The notified chemical was considered non-irritating to the skin under the conditions of the test.
TEST FACILITY	BASF (2017b)

B.3. Eye Irritation – *In Vitro* EpiOcular™

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 492 Determination of Ocular Irritation Potential Using the EpiOcular™ (Reconstructed Human Cornea-like Epithelium Model (RhCE) Test) Method
Vehicle	None
Remarks – Method	GLP compliant No significant protocol deviations. The MTT [(3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide, thiazolyl blue] assay was used to determine cell viability.

RESULTS

Test Material	*Mean OD_{570} of Duplicate Tissues*	*Relative Mean Viability (%)*
Negative Control	1.795	100
Test Substance	1.530	85.3
Positive Control	0.460	25.6

OD = optical density

Remarks – Results	The test substance was shown not to directly reduce MTT. The positive and negative controls performed as expected, confirming the validity of the test.
CONCLUSION	The notified chemical was considered non-irritating to the eye under the conditions of the test.
TEST FACILITY	BASF (2016d)

B.4. Skin Sensitisation – LLNA

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain	Mouse/CBA/CaO1aHsd
Vehicle	Propylene glycol
Preliminary study	Yes
Positive control	α-Hexylcinnamaldehyde at 25% concentration v/v in acetone/olive oil 4:1.
Remarks – Method	A pre-test with 25% test substance preparation showed statistically significant increase in ear weights, which was considered indication for ear irritation. Therefore the 25% preparation was the maximum concentration used in the main study.

RESULTS

Concentration (% w/w)	*Number and Sex of Animals*	*Proliferative Response (DPM/lymph node)*	*Stimulation Index (test/control ratio)*
Test Substance			
0 (vehicle control)	5F	550.8 ± 319.4	1.00
5%	5F	609.6 ± 161.5	1.1
10%	5F	515.2 ± 222.6	0.9
25%	5F	792.2 ± 204.2	1.4
Positive Control (HCA, alpha-hexyl cinnamaldehyde)			
25% in acetone:olive oil (4+1 v/v)		8170.5±	7.8

Remarks – Results

No deaths and no signs of systemic toxicity were reported. The stimulation index (SI) for increase in ^{3}H-thymidine incorporation into cells was less than 3 at all doses, indicating that the notified chemical is not a sensitiser.

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

CONCLUSION

There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical at up to 25% concentration.

TEST FACILITY

Envigo (2016)

B.5. 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

Salmonella typhimurium: TA1535, TA1537, TA98, TA100
Escherichia coli: WP2uvrA

Metabolic Activation System

S9 mix from phenobarbital/β-naphthoflavone induced rat liver

Concentration Range in Main Test

a) With metabolic activation: 33 - 5000 µg/plate
b) Without metabolic activation: 33 - 5000 µg/plate

Vehicle

Dimethyl sulfoxide

Remarks – Method

GLP compliant
No significant protocol deviations

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

No substantial increase in revertant colony numbers of any of the five tester strains was observed following treatment with the test substance at any dose level, with or without S9-mix.

	Vehicle and positive controls performed as expected, confirming the validity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BASF (2016e)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Transformation/dissolution in aqueous media

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 29 Transformation/dissolution of metals and metal compounds in aqueous media
Exposure Period	7 days
Auxiliary Solvent	None
Analytical Monitoring	Inductively Coupled Plasma – Mass Spectrometry (ICP-MS)
Remarks – Method	A screening test was conducted at pH 6 and 8.5. The highest leaching concentration was found at pH 6 in a screening test so a full test was run at this pH. No major deviations from the test guidelines were reported. The test loading rates were 1 mg/L (low), 10 mg/L (medium) and 100 mg/L (high). Leaching concentration was measured every 24 hours.

Results

Loading rates (mg/L)	Maximum dissolved Zn concentration at pH 6 (mg/L)
1	0.011
10	0.028
100	0.30

Remarks – Results	The measured concentration of components of the notified chemical were nearly constant with increasing leaching time, which indicated the leaching process was completed within 24 hours. Only zinc was detected (no other metal species were reported) and a maximum of 0.30 mg/L was determined at pH 6 and 0.03 mg/L at pH 8.5.
CONCLUSION	Zinc is leached from the notified chemical at a maximum concentration of 0.30 mg/L at pH 6.
TEST FACILITY	BASF (2016g)

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