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

PUBLIC REPORT

Niobium sulfur tin 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 the Environment and Energy.

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:

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**Director
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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/1438	Shepherd Color International Inc	Niobium sulfur tin zinc oxide	ND*	≤ 10 tonnes per annum	A pigment for industrial coatings and plastics

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the limited toxicity data provided, the notified chemical cannot be classified 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

Based on the low hazard and 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 and end use:
 - Local exhaust ventilation when the chemical is handled in powder form
 - Enclosed, automated systems where possible
 - Use of spray booths for spray or powder application, where possible.
- 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 and end use:
 - Avoid eye and skin contact and inhalation exposure
 - Avoid generation of dusts or aerosols
 - Clean up spills promptly
- 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 and end use:
 - Gloves and footwear
 - Protective clothing
 - Goggles
 - Appropriate respiratory protection (with particulate filter) 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.
- Where worker exposure to dusts may occur, atmospheric monitoring should be conducted to measure workplace concentrations during reformulation and end use of the notified chemical in order to keep dust levels below the exposure standard for tin dusts of 2 mg/m³ (Time-Weighted Average) (SWA, 2018).
- 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.

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.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical 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(1) of the Act; if
 - the notified chemical is to be used as a component of toys;
 - the notified chemical is to be used in food contact applications;
 - additional information on repeated dose toxicity becomes available for the notified chemical;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a pigment for industrial coatings and plastics, 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

This notification has been conducted under the cooperative arrangement with the USA. The health and environmental hazard assessment components of the USA report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Shepherd Color International Inc (ABN: 84 078 829 866)
Suite 24, 347 Bay Road
CHELTENHAM VIC 3192

NOTIFICATION CATEGORY

Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Assessed by a comparable agency

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: vapour pressure, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, flash point, flammability limits, autoignition temperature, explosive properties, oxidising properties, acute dermal toxicity, acute inhalation toxicity, repeated dose toxicity, genotoxic damage *in vitro*, ready biodegradability, bioaccumulation, fish toxicity, inhibition of bacterial respiration

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2012), EU-REACH

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Yellow 10C151

OTHER NAME(S)

Niobium Tin Zinc Pyrochlore; C.I. 777895; CP1047; EX1455; Yellow 30C152; YL0010P150; YL0010C151; Pigment Yellow 227; C.I. Pigment Yellow 227

CAS NUMBER

1374645-21-2

CHEMICAL NAME

Niobium sulfur tin zinc oxide

MOLECULAR FORMULA

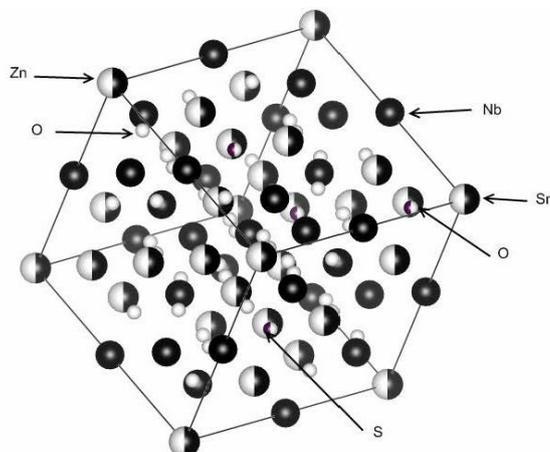
Nb.O.S.Sn.Zn

STRUCTURAL FORMULA

$\text{Sn}_{2-x}\text{Zn}_x\text{Nb}_2\text{O}_{7-x}\text{S}_y$ where $x = 0.1$ and $y = 0.2$ (information provided by the notifier)

The valency is 2+ for Tin, 2+ for Zinc, 5+ for Niobium, 2- for Sulfur and 2- for Oxygen

The notified chemical has a three-dimensional lattice structure depicted below:

**MOLECULAR WEIGHT**

533.1116 g/mol (nominal value)

3. COMPOSITION**DEGREE OF PURITY**

> 99%

IMPURITIES/RESIDUAL MONOMERS

None identified

ADDITIVES/ADJUVANTS

None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellow powder

Property	Value	Data Source/Justification
Melting Point/Boiling Point	No value determined	Based on a Differential Scanning Calorimetry (DSC) - Thermogravimetric Analysis (TGA) study, the chemical does not melt or boil, and decomposition begins at 350 °C
Density	4,300 kg/m ³ (temperature unspecified)	Measured
Vapour Pressure	Not determined	Not able to be measured, as not volatile.
Water Extraction	Solubility in deionised water was 4.1 mg/L for S, < 1.0 mg/L for Sn, 1.5 mg/L for Zn, < 1.0 mg/L for Ti and < 2.5 mg/L for Nb	Measured
Hydrolysis as a Function of pH	Not determined	Contains no hydrolysable functionalities
Partition Coefficient (n-octanol/water)	Not determined	Not relevant as it is an inorganic substance
Adsorption/Desorption	Not determined	Based on its expected low solubility in water, the notified chemical is expected to settle to sediment and sludge.

Dissociation Constant	Not determined	Limited dissolution, which is expected to lead to formation of ions under environmental conditions.
Particle Size	Inhalable fraction (< 100 µm): 100% Respirable fraction (< 10 µm): 100% MMAD* = 0.776 µm	Measured
Flash Point	Not determined	The chemical is a non-volatile inorganic solid
Solid Flammability	Not flammable	Based on the observation in DSC - TGA
Autoignition Temperature	Not expected to autoignite	Based on the observation in DSC-TGA and in a thermal stability test on bulk powder. In the latter test, an exothermic reaction commenced from 180°C and reached 702°C
Explosive Properties	Not expected to be explosive	Measured in a dust explosivity test
Oxidising Properties	Not determined	Not expected to be oxidising based on the structure.

* MMAD = Mass Median Aerodynamic Diameter

DISCUSSION OF PROPERTIES

For full 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 use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for physical 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 be imported at 100% into Australia.

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>	2	2	2	4	6

PORT OF ENTRY

Melbourne, Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

Shepherd Color International Inc

TRANSPORTATION AND PACKAGING

The notified chemical will be transported in the original import containers (5 kg plastic lined cardboard boxes and 25 kg plastic lined cardboard boxes) by road from the wharf to Shepherd Color International Inc.'s warehouse. It will be transported as required by truck to a variety of customers around Australia.

Industrial coatings

After production of liquid waterborne paint formulations or liquid solvent borne paint formulations, the formulated coatings containing the notified chemical at up to 30% will be packed in 1 L steel cans, 5 L steel cans, 20 L steel pails and 200 L steel drums, prior to delivery to industrial coating applicators.

After production of solid powder coating paint formulations, the formulated coatings containing the notified chemical at approximately 10% will be packed in 5 kg plastic lined cardboard boxes, 25 kg plastic lined cardboard boxes, and 200 kg plastic lined cardboard kegs, prior to delivery to industrial coating applicators.

Plastic masterbatch compounding

After production of solid masterbatch formulations, the formulated masterbatches containing the notified chemical at 40-58% will be packed in 5 kg plastic lined cardboard boxes, 25 kg plastic lined cardboard boxes, and 200 kg plastic lined cardboard kegs, prior to delivery to thermoplastic resin moulders of engineering thermoplastics.

USE

The notified chemical will be used as a pigment to add colour to industrial surface coatings containing the notified chemical at up to 30% and to plastic masterbatches at 40-58%, resulting in plastic articles containing the notified chemical at 1-2%. The notified chemical will not be used in toys or in food contact applications.

OPERATION DESCRIPTION

Industrial coatings

Industrial paint manufacturing companies will add the notified chemical into their waterborne or solvent borne liquid paint formulations at up to 30% or into their solid powder coatings at approximately 10%.

For liquid paint formulation, a spear pump is used to transfer the notified chemical to a closed mixing kettle to which binder resins, water or solvents and other additives are added to achieve appropriate application properties. For powder coating formulation, a spear pump is used to transfer the notified chemical to the hopper of a horizontal blending extruder to which powder coating resins such as solid epoxy resins and solid polyester resins and other additives are added to achieve appropriate application properties.

The coatings containing the notified chemical will be predominantly applied in professional spray workshops or in automated application plants.

At the industrial coating applicators' sites, the liquid formulated coatings containing the notified chemical at up to 30% will be applied by a variety of application techniques including coil coating, dip coating, wipe coating (by hand) and spray coating. Formulated powder coatings containing the notified chemical at approximately 10% will be applied by a variety of techniques including electrostatic spray coating, dip coating, and fluidised bed coating.

Plastic masterbatch compounding

Plastic masterbatch compounders will incorporate the notified chemical at 40-58% into thermoplastic masterbatch formulations, for supply to thermoplastic moulders.

Thermoplastic resin moulders will in turn incorporate the pigmented masterbatch in ratios of 2.5-3.5% into their plastic formulations and produce finished articles through injection moulding, extrusion or blow moulding. Thus, the finished moulded articles will contain 1-2% of the notified chemical.

These finished moulded articles may be used in a variety of applications such as plastic items for consumer use or for industrial applications.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport workers	8	10
Distribution workers	4	20
Warehousing staff – Third-party	1	40
Warehousing staff – customers	1	60
Coating production operators	3	60

Coating production quality control technicians	3	60
End use coaters	5	30
Plastic masterbatch compounding operators	3	60
Plastic masterbatch compounding quality control technicians	3	60
End use thermoplastic resin moulders	5	30

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the notified chemical at up to 100% concentration only in the event of accidental rupture of containers.

Industrial coatings

Dermal, inhalation and ocular exposure of coating formulation manufacturing workers to the notified chemical in powder form at up to 100% may occur when manually weighing, connecting and disconnecting spear pumps, charging powder into the blending vessels, sampling from the blending vessel, during routine cleaning and maintenance of equipment, and cleaning up of spills or leaks. Dermal and ocular exposure will be minimised by the use of personal protective equipment (PPE) worn by workers, such as goggles, protective clothing, gloves and footwear. Inhalation exposure is expected to be minimised by the local exhaust ventilation (LEV) that will be employed in areas where weighing and charging of the blending vessels occurs.

Inhalation exposure of waste recycling workers to dusts of the notified chemical may also occur during the recycling of the chemical's packaging. Such exposure is expected to be minimised by the LEV employed in areas where drum recycling occurs and by workers wearing PPE.

Dermal, ocular and inhalation exposure of paint applicators (liquid and powder) to the notified chemical at up to 30% may occur when manually connecting the packaged coatings to the application equipment, during paint application, and during routine cleaning and maintenance of painting equipment, and cleaning up of spills or leaks.

Dermal and ocular exposure to the notified chemical will be minimised by the use of LEV in the painting areas and by workers wearing PPE. Workers in spray booths will wear a full body suit with an air makeup hood. Inhalation exposure during painting will be minimised by conducting spray operations within paint booths with local exhaust ventilation/extraction.

Where any LEV is not adequate during the reformulation, recycling and end uses, the notifier confirmed that workers would be required to wear a full or half facepiece respirator with a Class P1 filter.

Plastics manufacture

Dermal, inhalation and ocular exposure of plastic masterbatch formulation workers to the notified chemical at up to 100% may occur when manually weighing, connecting and disconnecting spear pumps, charging the extruder hopper and nibber, sampling from the blending vessel, during routine cleaning and maintenance of equipment, and cleaning up of spills or leaks. The exposure will be minimised by the use of LEV in the areas where weighing and charging of the extruder hopper and nibber occurs, and by workers wearing PPE.

Inhalation exposure of waste recycling workers to dusts of the notified chemical may also occur during package recycling. Such exposure is expected to be minimised by the LEV employed in areas where package recycling occurs and workers wearing PPE.

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

Where any LEV is not adequate during reformulation, recycling and end uses, the notifier confirmed that workers would be required to wear a full or half facepiece respirator with a Class P1 filter.

6.1.2. Public Exposure

The products containing the notified chemical are intended for use in industrial situations and will not be available for public use, therefore direct exposure to the notified chemical is not expected to occur.

The public may come into contact with the painted surfaces containing the notified chemical after application to substrates or with the moulded plastic items after moulding. The chemical will not be used in toys or in food contact applications. Once the paint is cured or the plastic item has been moulded, the notified chemical is expected to remain bound within the cured inert polymer matrix and not be available for exposure. This is supported by a migration study (refer to Appendix A) on the notified chemical as 10% pigment in low density polyethylene chips. The study showed the migration of niobium, tin and zinc into ethanol was in most cases below the level of detection. Overall public exposure to the notified chemical is expected to be negligible.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation (<i>in vitro</i>) human skin model test	not irritating
Eye irritation (<i>in vitro</i>) bovine corneal opacity and - permeability test (20%)	not corrosive or severely irritating to the eye
Guinea pig, skin sensitisation –non-adjuvant test.	no evidence of sensitisation
Mutagenicity (<i>in vitro</i>) – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution

The potential for absorption across biological membranes may be limited by the low solubility in water. Airborne dusts of the notified chemical will be easily inhaled given that 100% are within the respirable size range. 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 lung overloading. If particles also deposit in the nose, throat and upper respiratory tract, a large proportion of these are likely to be cleared by mucociliary action and orally ingested.

Acute toxicity

The notified chemical was found to have low acute oral toxicity in rats. No acute dermal or inhalation toxicity data are available. The SDS of the notified chemical notes that inhalation of dusts may cause respiratory irritation.

Irritation

Based on the results of an *in vitro* skin irritation study (human skin model test), the notified chemical was considered as not irritating to skin.

In an eye irritation (*in vitro*) bovine corneal opacity and permeability (BCOP) test, the notified chemical as a 20% suspension was not classifiable as an ocular corrosive or severe irritant. This test does not consider whether the chemicals would be classified as eye irritants. Therefore negative results are inconclusive for eye irritation. An in-house interpretation of the BCOP study results considered the chemical to be mildly irritating to the eyes. It is noted that the BCOP protocol does not measure conjunctival effects. Also, the BCOP test could produce high false negative results for solids (OECD TG 437).

No data are available on respiratory irritation.

Sensitisation

Based on the results of a guinea pig study (Buehler), the notified chemical was not considered to be a skin sensitizer.

Repeated dose toxicity

No repeated dose toxicity study was available for the notified chemical. Information on the hazard characteristics of metal compounds, Nb, Sn and Zn may be indicative of potential hazards of the notified chemical, if there is significant exposure.

Pulmonary changes in tin workers and a benign pneumoconiosis (stannosis) were attributed to the inhalation of tin oxide, with symptoms including dyspnea (breathing difficulty) and decreased pulmonary function (Patty's Toxicology 2012a, b, c, d, e, CDC 2018a). Impaired lung function in workers from inhalation of zinc oxide

fumes or zinc chloride smoke has been reported (Patty's Toxicology 2012a, b, c, d, e), as well as an acute inflammatory airway reaction known as metal fume fever (Patty's Toxicology 2012f, g, CDC 2018b).

Rats were fed with diets containing 0 (control), 0.03%, 0.1%, 0.3%, or 1.0% of various salts or oxides of tin for 28 days. There was no observed change in mortality, appearance/behaviour, food intake, body weight, or a wide range of blood, urine and tissue endpoints. This particular study used insoluble tin compounds such as stannous sulfide, stannous oleate, or stannous or stannic oxides (Patty's Toxicology 2012h).

When niobium pentachloride was fed to CFN rats at dietary levels of 0.01%, 0.1%, or 1% for 12 weeks, the animals did not appear to differ from controls, except for effects on the liver (Patty's Toxicology 2012i). These effects consisted of perinuclear vacuolation of the parenchymal cells and coarse granulation of the cytoplasm.

While zinc is essential for humans and animals, toxicity has been associated with excess exposure. A range of systemic effects have been reported, including effects in the haematological and gastrointestinal systems. Adverse effects on reproduction have also been reported (Patty's Toxicology 2012j).

Mutagenicity/Genotoxicity

The notified chemical was not considered to be mutagenic in a bacterial reverse mutation assay.

Niobium pentachloride was negative for mutagenic effects in a recombination assay performed in wild and recombination-deficient strains of *Bacillus subtilis* (Patty's Toxicology 2012k).

Health hazard classification

Based on the limited toxicity data provided, the notified chemical cannot be classified 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

6.3.1. Occupational Health and Safety

Based on the data provided, the notified chemical is not classified as a skin irritant or severe eye irritant, but it may have some potential for mild eye irritation. Absorption across biological membranes is likely to be limited by its low water solubility. Repeated dose toxicity is not available on the notified chemical. Information on inorganic substances containing the same chemical elements indicates a concern for lung overloading and adverse respiratory effects if particles are inhaled at high doses.

The notified chemical is imported in powder form, with respirable particle size. The highest potential for inhalation exposure of workers is during weighing and transfer of the notified chemical in powder form, in the first stages of the processes which incorporate it into coatings or plastic. Other stages where inhalation could occur are during further processing and application of powder coatings, and during spray application of liquid coatings. Dermal or ocular exposure could occur at all stages of processing

The notifier has advised that transfer of the chemical in powder form during formulation will occur under local exhaust ventilation, which is expected to reduce worker exposure via inhalation. Workers are also expected to be trained in pigment handling techniques. According to the notifier, appropriate respiratory protection will be used during any processes where dust is generated or inhalation may occur, which would reduce potential worker exposure further.

Safe Work Australia has recommended exposure standards for dusts and fumes of related chemicals: Time-Weighted Average (TWA) for tin oxide (2 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) (SWA, 2018). The lower TWA value for Tin would be a useful guideline if air monitoring of the notified chemical is performed at workplaces.

The notified chemical is not expected to be inhaled when reformulated with liquid components, but workers could experience dermal and eye exposure through splashes and spills, therefore PPE (goggles, protective clothing, gloves and footwear) would reduce skin and eye contact during both formulation and end use of coatings.

Inhalation exposure to the notified chemical may occur during end use spray operations (at concentrations of up to 30%), particularly for powder coatings. According to the notifier, exposure is expected to be reduced by various control measures, including use of spray booths, 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 incorporated into the coating or plastic matrix and will not be available for exposure. Therefore the risk to workers from exposure to the notified chemical in articles and cured coatings is expected to be low.

Overall, the risk to workers during coatings and plastics manufacture is not unreasonable if the proposed engineering controls are in place, safe work practices are implemented and PPE are used.

6.3.2. Public Health

The public is expected to have no exposure to the notified chemical in uncured form. The public may come into contact with coated surfaces or moulded plastic items containing the notified chemical. Once the paint is cured or the plastic item has been moulded, the notified chemical is expected to remain bound within the matrix and not be available for exposure. Based on negligible exposure to the public, the risk to public health is not considered to be unreasonable.

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 for formulation into paints and plastic moulding operations. Environmental release of the notified chemical is expected to be limited to accidental spills arising during the production of paint formulations and plastics moulding operations. Any spills will be collected using adsorbent material and sent to landfill by licensed waste contractors.

The coatings containing the notified chemical will be predominately applied in professional spray workshops with filtered extraction systems at industrial sites onto primed metallic (steel or aluminium) structures. They will also be applied in automated application plants including coil coating plants.

Plastic masterbatch compounders will incorporate the notified chemical in ratios of 40-58% (depending upon desired properties) into thermoplastic masterbatch formulations.

RELEASE OF CHEMICAL FROM USE

The paints containing the notified chemical will be used by industry as a protective coating/primer for structural steel. Industrial paint companies will add the notified chemical, generally in ratios of 10-15% (depending upon desired colours), into their waterborne or solvent borne liquid paint formulations or about 10% into their solid powder coatings. At the industrial powder coating applicators' sites, the formulated powder coatings containing the notified chemical at levels of about 10% of notified chemical mixed with solid binder resins and other additives will be applied by a variety of application techniques including electrostatic spray coating, dip coating, and fluidised bed coating.

The transfer efficiencies of brushes and rollers is high, particularly for paints of high viscosity, it is estimated that < 1% of the notified chemical will be released as a result of application through splashes and drips. It is expected that these releases will be left on the ground, collected with adsorbent and disposed of through industrial waste to landfill. Coating formulations containing the notified chemical are also applied by spray techniques. It is anticipated that approximately 20-30% of the coating product will form overspray and be collected as waste material. As the application of coatings will be conducted at industrial sites in designated spray booths, the overspray will be captured in the spray booth on Kraft paper or newspaper and is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Waste of notified chemical will be generated annually during the manufacture of the paint, in cleaning coating equipment and as residues in packaging of the products containing the notified chemical (paper bags of the imported product and drums of the formulated paints).

The bags used to import the chemical, containing residual chemical, will be disposed of to landfill. Residues in paint drums are expected to account for < 0.1% of the imported chemical and are expected to be disposed of to landfill.

The majority of the notified chemical will share the fate of paints into which it has been incorporated. These are expected to share the fate of the surfaces to which they have been applied at the end of their useful life and metal will be reclaimed during thermal decomposition process. The plastic articles incorporating the notified chemical may be recycled but ultimately at the end of their useful lives will be disposed of to landfill.

7.1.2. Environmental Fate

The Bioconcentration Factor (BCF) of environmental niobium, sulfur, tin and zinc are expected to be very low. Therefore, the notified chemical is not expected to be bioaccumulative in the environment. Further, the notified chemical is not expected to be bioavailable as it has low water solubility. Notified chemical sent to landfill is not expected to be mobile and will remain as an inert matrix. Any notified chemical released to the aquatic environment is expected settle to sludge in sewage treatment plants or partition to the sediment.

7.1.3. Predicted Environmental Concentration (PEC)

The notified chemical is not expected to be present at significant concentrations in the aquatic environment because of the very low potential for direct release to surface waters based on its use pattern. A Predicted Environmental Concentration (PEC) therefore has not been calculated.

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.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Daphnia Toxicity	EC50 (48 h) >100 mg/L WAF*	Not harmful to aquatic invertebrates
Algal Acute Toxicity	ErC50 (72 h) > 100 mg/L WAF*	Not harmful to algae

*Water Accommodated Fraction (WAF)

The ecotoxicity endpoints for the notified chemical are much higher than its water solubility limit. Hence, the notified chemical is not expected to be harmful to aquatic organisms at its solubility limit in the aquatic environment. Therefore, under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009), the notified chemical is not expected to be harmful to fish, invertebrates, algae, sediment dwellers and terrestrial organisms on an acute or long term basis and is not formally classified under the GHS.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated since the notified chemical is not considered to be harmful up to the limit of its solubility in water.

7.3. Environmental Risk Assessment

The risk quotient ($Q = PEC/PNEC$) has not been calculated for the notified chemical as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern. At the end of their useful life, articles containing the notified chemical are expected to be disposed of to landfill. In cured paints and plastic articles the notified chemical will be bound within the inert polymer matrix and is unlikely to leach or be bioavailable. Thermal decomposition of the notified chemical will produce water and oxides of niobium, sulfur and zinc. On the basis of the low aquatic hazard and limited aquatic exposure, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point Chemical does not melt, decomposition begins at 350 °C

Method Differential Scanning Calorimetry (DSC) - Thermogravimetric Analysis (TGA)
Remarks The test substance did not have a melting point, because on heating it decomposed without melting. The data showed that the test substance, when heated in air, began to decompose around 350 °C. Between 350 and 440 °C. There was oxidation of the tin from Sn(II) to Sn(IV). The physical state of the substance was not changed and nothing was emitted. At higher temperatures, between 750 and 900 °C, there were two successive oxidations of the sulfur that resulted in elimination of acidic sulfur oxide vapours totalling 1% of the material weight. The remaining material remained a solid mixed-metal oxide.

Though the decomposition was through an oxidation process, testing showed that the substance was neither flammable nor explodable.

Density 4,300 kg/m³ (temperature unspecified)

Method Followed the broad guidelines in industry standard ATM D153-84
Remarks The test substance as a dry powder was tested using an Accupyc 1330 Pycnometer.
Test Facility The Shepherd Color Company (2012)

Water Extraction

Element	Deionised water (mg/L)	pH = 5.5 buffer (mg/L)	pH = 8 buffer (mg/L)
Soluble S	4.1	3.3	30
Soluble Sn	< 1.0	2.1	12
Soluble Zn	1.5	29	< 1.0
Soluble Ti	< 1.0	< 1.0	< 1.0
Soluble Nb	< 2.5	< 2.5	27

Method European Test Method EN-71.3 (Safety of toys- Part3: Migration of certain elements). SCTM 271 (European Standard for Safety of Toys)

The sample was mixed with 50 times its mass of deionised water. The mixture was heated to 37 ± 2°C and stirred for one hour. After one hour, the stirring was discontinued and the sample was allowed to stand at 37°C for another hour. The sample was then filtered. The filtrate was analysed for the metals of interest.

Remarks The method covers the migration of metals in fine powder metal oxide or mixed metal oxide pigments and does not cover any of the other materials which are listed in the European Test Method EN-71.3.

Test Facility This method assumes that the sample material meets the 0.5 mm sieve test.
The Shepherd Color Company (2018)

Particle Size

Mass Median Aerodynamic Diameter = 0.776 µm
 Median Aerodynamic Diameter = 0.809 µm
 Mode = 0.877 µm
 Standard Deviation = 0.266 µm

Range (µm)	Mass (%)
< 100 µm	100
< 10 µm	100
≤ 2.269 µm	100
≤ 1.005 µm	82.167
≤ 0.339 µm	0.334

Remarks Tested on laser diffraction particle size analyser.
Test Facility The Shepherd Color Company (undated)

Explosive Properties	No explosion
Method	ASTM Standard E1226, (1995) Explosion Protection systems Part 1: Determination of Explosion Indices of Combustible Dusts in Air ISO 6184/1, ISO Geneva
Remarks	Measures the explosion severity of a powder sample in a 20 L Sphere Apparatus. Different dust concentrations within the test chamber were measured. The study authors noted that the results refer only to the sample tested, and may vary with particle size and moisture content.
Test Facility	Chilworth Technology (2012)

Explosive Properties	Exothermic reaction occurred
Method	Bulk Powder Test – Diffusion Cell: Thermal Stability Screening Test. The test is stated to meet the specification in “Prevention of Fire and Explosions in Dryers”, Institution of Chemical Engineers (1990), pp21-23
Remarks	The purpose of the test is to simulate conditions in silos or bags and at the bottom of dryers where material can collect in bulk, and is a screening test for self heating and self ignition. Three samples of material were heated in an oven to 400 °C. The exotherm onset temperature and maximum temperature reached were recorded. An exothermic reaction was observed during the test, commencing at 180°C and rising to 702°C.
Test Facility	Chilworth Technology (2012)

Migration Study	There was negligible or no detected niobium, tin and zinc in the migration test solution of 95% ethanol.
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Method Migration tests from low-density polyethylene chips (chosen as the worst case polymer) containing the notified chemical at 10% loadings were carried out using the food-simulating solvent, 95% ethanol. Two separate experiments were performed:
 (1) 2 hours contact time at a high temperature (101-105 °C);
 (2) 2 hours contact time at a high temperature followed by 10 days at 40°C.
 Aliquots were taken from each migration test cell at the end of the contact time.

The detection limit or limit of determination (LOD) was calculated based on 3 times the standard deviation of all calibration standard blank intensity readings. The limit of quantitation (LOQ) was calculated based on 10 times the standard deviation of all the calibration standard blank intensity readings.

Results	Element	LOD	LOQ
	Zn (mg/L)	0.03	0.09
	Nb (mg/L)	0.01	0.03
	Sn (mg/L)	0.02	0.07

The following levels of Zn, Nb and Sn were detected:

- levels of < 0.03 mg/L Zn in solution samples (equivalent to 0.048 µg/cm² for the chip area tested) were detected in all 8 samples for the 2 hour migration study and in 7 out of 8 samples for the 10 day migration study
- Levels of < 0.01 mg/L Nb in solution samples (equivalent to 0.0155 µg/cm² for the chip area tested) were detected in all 16 samples for the 2 hour and 10 day migration studies
- Levels of < 0.02 mg/L Sn in solution samples (equivalent to 0.032 µg/cm² for the chip area tested) in 6 out 8 samples for the 2 hour migration study and in all 8 samples for the 10 day migration study

Test Facility The Shepherd Color Company (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Notified chemical
METHOD	U.S. EPA Health Effects Test Guidelines, OPPTS 870.1100 Up and Down Procedure
Species/Strain	Rat/Sprague-Dawley albino
Vehicle	Distilled water
Remarks - Method	No protocol deviations

RESULTS

Group	Number and Sex of Animals	Dose (mg/kg bw)	Mortality
1	1 F	175	0/1
2	1 F	550	0/1
3	3 F	2,000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No signs of gross toxicity, adverse pharmacologic effects or abnormal behaviour were noted in animals.
Effects in Organs	No gross abnormalities were observed for any animals when necropsied at the end of 14-day observation period.
Remarks - Results	All animals gained body weight and appeared active and healthy during the study.

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

TEST FACILITY Product Safety Labs (2012a)

B.2. Irritation – skin (*in vitro* Human Skin Model Test)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 439 <i>In vitro</i> Skin Irritation: Reconstructed Human <i>Epidermis</i> Test Method (2010)
Vehicle	Distilled water was applied to the epidermal surface to improve the contact between the powder and the epidermis.
Remarks - Method	The protocol did not mention whether the test substance had been ground.

RESULTS

Test material	Mean OD ₅₅₀ of triplicate tissues	Relative mean Viability (%)	SD of relative mean viability
Negative control	1.103	100	11.0
Test substance	1.022	92.6	3.6
Positive control	0.032	2.9	0.1

OD = optical density; SD = standard deviation

Remarks - Results The preliminary test showed no non-specific reduction of MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-Diphenyltetrazolium Bromide) compared to the solvent, and not colouring potential of the test substance that would interfere with the test.

As the mean relative tissue viability (% negative control) was $\geq 50\%$ after 15 min treatment and 42 h post incubation, the test substance was not considering a skin irritant requiring classification.

The validity of the study was confirmed by the concurrent negative and

positive controls.

CONCLUSION The notified chemical did not meet the criteria for classification as a skin irritant under the criteria of the test.

TEST FACILITY BSL Bioservice (2012a)

B.3. Irritation – eye (*in vitro* Bovine Corneal Opacity and Permeability Test)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants (2009)

Vehicle Physiological saline 0.9% NaCl

Remarks - Method Under this protocol, a substance that induces an IVIS ≥ 55.1 is considered to be an ocular corrosive or severe irritant. The notified chemical was diluted to 20% in physiological saline, as suggested for non-surfactant solids. Based on that it is expected the final test substance would be a dispersion.

RESULTS

<i>Test material</i>	<i>Mean opacities of triplicate tissues</i>	<i>Mean permeabilities of triplicate tissues</i>	<i>IVIS</i>
<i>Vehicle control</i>	-0.33	0.007	-0.23
<i>Test substance*</i>	18.00	-0.001	17.99
<i>Positive control*</i>	174.67	1.902	203.20

SD = Standard deviation; IVIS = *in vitro* irritancy score

*Corrected for background values

Remarks - Results The validity of the study was confirmed by the concurrent negative (vehicle) and positive controls.

The test substance had an IVIS of < 55.1 and therefore is not considered an ocular corrosive or severe irritant. The study authors also used an in-house classification system to estimate that the chemical was a mild irritant.

The OECD test guideline notes that the BCOP has a high false negative rate for solids in the validation database.

CONCLUSION The notified chemical as a 20% dispersion was not an ocular corrosive or severe eye irritant under the conditions of the test.

TEST FACILITY BSL Bioservice (2012b)

B.4. Skin sensitisation - Buehler Method

TEST SUBSTANCE Notified chemical

METHOD EC Directive 96/54/EC B.6 Skin Sensitisation - <Buehler Method> (2004)

Species/Strain Guinea pig/Hartley albino

PRELIMINARY STUDY Maximum Non-irritating Concentration: 84% in a 2% mixture of carboxymethylcellulose (CMC) in distilled water
topical: 84%, 63%, 42%, 21%

MAIN STUDY

Number of Animals Test Group: 30 Control Group: 10

Vehicle The test substance, as a powder material with lumps, was moistened with a 2% w/v mixture of CMC in distilled water to enhance skin contact prior to the application, leading to a use concentration of 84%.

Positive control Not conducted in parallel with the test substance, but had been conducted

INDUCTION PHASE	previously in the test laboratory using α -hexylcinnamaldehyde. Induction Concentration: topical: 84%
Signs of Irritation	Very faint erythema was noted for some test sites during the induction phase.
CHALLENGE PHASE challenge	topical: 84%; 27 days after the first induction dose
Remarks - Method	A naïve control group was used for the challenge stage only. No protocol deviations were noted by the study authors.

RESULTS

Animal	Challenge Concentration	Number of Animals Showing Skin Reactions after: challenge	
		24 h	48 h
Test Group	84%	0/20	0/20
Control Group	84%	0/10	0/10

Remarks - Results In the challenge phase, very faint erythema was noted at three test sites 24 hours after challenge, but had cleared from these sites by 48-hours. Similar effects were seen in the naïve controls at challenge.

In the challenge stage of the historical positive validation study, faint erythema was seen in 3/20 animals at 24 h, persisting as faint or very faint erythema at 48 h. Several other animals in both the test and naïve control groups showed very faint erythema.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY Product Safety Labs (2012b)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test (1997)
Plate incorporation procedure (test 1)/Pre incubation procedure (test 2)

Species/Strain *Salmonella typhimurium*: TA1535, TA1537, TA98, TA100
Escherichia coli: WP2uvrA

Metabolic Activation System Rat liver S9 homogenate metabolising system (induced with phenobarbital/ β -naphthoflavone)

Concentration Range in Main Test a) With metabolic activation: 0, 31.6, 200, 316, 1,000, 2,500 and 5,000 μ g/plate
b) Without metabolic activation: 0, 31.6, 200, 316, 1,000, 2,500 and 5,000 μ g/plate

Vehicle Suspension in distilled water

Remarks - Method Concentrations for the main study were determined by a preliminary toxicity test. The particle size of the notified chemical in the suspension was not provided.

RESULTS

Metabolic Activation	Test Substance Concentration (μ g/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent	> 5,000			
Test 1		> 5,000	\geq 2,500	negative
Test 2		> 5,000	\geq 2,500	negative

<i>Present</i>	> 5,000			
Test 1		> 5,000	$\geq 2,500$	negative
Test 2		> 5,000	$\geq 2,500$	negative
Remarks - Results	<p>No toxic effects or biologically relevant increases in revertant colony numbers were noted with any of tester strains in either the presence or absence of S9 activation.</p> <p>The concurrent positive and negative controls produced satisfactory responses, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.</p>			
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.			
TEST FACILITY	BSL Bioservice (2012c)			

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test – Static.
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	Not reported
Water Hardness	200 mg/L as CaCO ₃
Analytical Monitoring	Inductively coupled plasma-mass spectrometer (ICP-MS)
Remarks - Method	Based on the results of the range-finding test, which showed that there was no immobility of <i>Daphnia</i> exposed to nominal test substance concentrations up to 100 mg/L, a "Limit Test" was conducted at a single nominal concentration of 100 mg/L.

No significant deviations from the test guidelines were reported. The test solution was prepared as a Water Accommodated Fraction (WAF). The WAF solution was prepared by adding test substance (100.2 mg) to the aqueous test medium (1 L). The mixture was stirred for 2.5 hours. The mixture was allowed to stand and the supernatant liquor was filtered. The aqueous phase containing the soluble substances, the WAF, was taken to perform the test.

RESULTS

Concentration mg/L (WAF)	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48 h
Control	20	0	0
100	20	0	0

EL50	> 100 mg/L at 48 hours
NOEL	≥ 100 mg/L
Remarks - Results	The validity criteria for the test were satisfied. Dissolved oxygen concentration at the end of the test was ≥ 3 mg/L in the control and test vessels. The result is based on nominal concentration.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates.

TEST FACILITY Aquatox (2012a)

C.1.2. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	Freshwater green algae (<i>Pseudokirchneriella subcapitata</i>)
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: Not reported
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Inductively coupled plasma-mass spectrometer (ICP-MS)
Remarks - Method	No significant deviations from the test guidelines were reported. The test solution was prepared as a Water Accommodated Fraction (WAF). The WAF solution was prepared by adding test substance (100.05 mg) to the filtered algal nutrient medium (1 L). The test mixture was stirred for 1

hour . The mixture was allowed to stand for 48 hours and the supernatant liquor was filtered. The aqueous phase containing the soluble substances, the WAF, was taken to perform the test.

RESULTS

	<i>Biomass</i>		<i>Growth</i>	
	<i>EL50</i> <i>mg/L at 72 h</i>	<i>NOEL</i> <i>mg/L</i>	<i>EL50</i> <i>mg/L at 72 h</i>	<i>NOEL</i> <i>mg/L</i>
	> 100	Not reported	> 100	Not reported

Remarks - Results

The validity criteria for the test were satisfied. Biomass in control test vessels increased by a factor of ≥ 16 times after 72 hours. The mean coefficient of variation in the control culture was $\leq 35\%$. The coefficient of average growth rate in the replicate control culture was $\leq 7\%$. The result is based on the nominal concentration.

CONCLUSION

The notified chemical is not harmful to algae.

TEST FACILITY

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