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

PUBLIC REPORT

Slags, ilmenite electrothermal smelting

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
NICNAS**

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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/1504	Tronox Management Pty Ltd	Slags, ilmenite electrothermal smelting	ND*	≤ 200,000 tonne/s per annum	Production of titanium dioxide pigment and titanium alloys

*ND = not determined

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 for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

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 assessed use pattern, the notified chemical is not expected 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:
 - Enclosed, automated processes, where possible
 - Local ventilation systems, 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:
 - Avoid breathing dusts
 - Avoid leaks and spills during use
- 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:
 - Respiratory protection if ventilation is inadequate

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

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

Public Health

- The following measures should be taken by formulators to minimise public exposure to the notified chemical:
 - Avoid creating dusty conditions and prevent wind dispersal

Environment

- The following control measures should be implemented by the notifier to minimise environmental exposure during manufacture, formulation, use of the notified chemical:
 - Avoid dispersal of spilled material. Recycle, if possible, otherwise dispose of in accordance with local regulations

Disposal

- The notified chemical should be disposed of to landfill.

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

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(2) of the Act; if
 - the function or use of the chemical has changed from an ingredient of titanium dioxide pigment and titanium alloys, 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.

(Material) Safety Data Sheet

The (M)SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Tronox Management Pty Ltd (ABN: 009 363 364)
1 Brodie Hall Drive
Technology Park
BENTLY WA 6102

NOTIFICATION CATEGORY

Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

European Union (2006)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

CP Slag, CP Slag Fines, Titanium Slag

CAS NUMBER

91081-64-0

CHEMICAL NAME

Upgraded ilmenite slag

OTHER NAME(S)

UGI, upgraded ilmenite, titanium slag, slag ilmenite electrothermal smelting, titanium dioxide (TiO₂) slag

MOLECULAR FORMULA

M₃O₅, M = Majority TiO₂

STRUCTURAL FORMULA

A structural formula is not available. The notified chemical is an inorganic mono-constituent structure which consists primarily of TiO₂, FeO, Al₂O₃, SiO₂, MgO and other metal oxides. The exact composition of the notified chemical is dependent on the source from which it is mined.

The structure is comprised of a titanate and a glassy silicate phase. The titanate phase (equivalent of 91–99% w/w) is a solid solution predominantly arranged in a dual pseudobrookite-karrooite crystal structure. It is not possible to identify the major, minor and trace elements of the structure as free oxides in the structure. Some rutile is also present in the titanate phase (indicating high purity upgraded ilmenite slag). The glassy silicate phase (generally < 5–9%) is in the form of small inclusions within the titanate phase. The titanium content of the notified chemical is often commercially expressed in terms of TiO₂ equivalent for which the notified chemical has a minimum equivalent of 78%.

MOLECULAR WEIGHT

79.866 (for the main constituent, TiO₂)

ANALYTICAL DATA

Reference NMR, IR, HPLC, GC, GPC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

78% TiO₂

91–99% Titanate (w/w) with generally < 5% glassy silicate phase

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)

The titanium content of the notified chemical is often commercially expressed in terms of TiO₂ equivalent for which the notified chemical has a minimum equivalent of 78%. The major impurities found in both phases of the notified chemical are iron, aluminium, calcium, magnesium, manganese, chromium and vanadium.

ADDITIVES/ADJUVANTS

None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Brown to black, odourless granular solid.

Property	Value	Data Source/Justification
Melting Point	1,550–1,850 °C	(M)SDS/ Siemens 2008 OECD 103/EU
Boiling Point	Not determined	(M)SDS/ Siemens 2008 OECD 103/EU
	> 600 °C 101.3 kPa	
Density	3,600–4,100 kg/m ³ at 20 °C	(M)SDS
Vapour Pressure	Not determined	Solid with melting point > 300 °C.
Water Solubility	≤ 19 µg/L	Measured
Hydrolysis as a Function of pH	Not determined	Water insoluble solid
Partition Coefficient (n-octanol/water)	Not determined	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	No dissociable functionality.
Particle Size	d50 = 55–800 µm*	Measured
	Inhalable fraction	
	2–80% < 100 µm	
	0–10% < 10 µm	
	MMAD** of airborne particles	
	= 27–70 µm	
Flash Point	Not applicable	(M)SDS/High melting point inorganic solid.
Flammability	Predicted non-flammable	(M)SDS/solid with no functionality
Autoignition Temperature	Predicted not to auto-ignite	Measured/screening test DSC
Explosive Properties	Non-explosive	Measured/screening test DSC
Oxidising Properties	Predicted negative	M)SDS/ lacks oxidising functionality

* d50 is the median of the particle size distribution. The range is due to measurements for nine feedstock ores of the notified chemical

** MMAD = Mass Median Aerodynamic Diameter

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

The notified chemical will be introduced as a granular solid with a median particle size between 55 and 800 µm depending on the production source (data from nine typical sources were provided). Particle size data was measured using a rotating drum method to simulate dusts that may be generated from mechanical agitation in an occupational setting. The MMAD of airborne particles was measured at 27–70 µm. The inhalable fraction

(< 100 µm) was measured between 2 and 80 %. The respirable fraction (< 10 µm) was measured between 0 and 10%. There are low amounts of respirable particles while the inhalable fraction varies widely.

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 hazard classification according to the *Globally Harmonised System for the 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

Imported in bulk (ship and road train) as a granular solid.

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

Year	1	2	3	4	5
Tonnes	< 200,000	< 200,000	< 200,000	< 200,000	< 200,000

PORT OF ENTRY

Bunbury, WA

IDENTITY OF MANUFACTURER/RECIPIENTS

Tronox Limited/Tronox Management Pty Ltd/Pigment Holdings Pty Ltd
Kwinana, Henderson and Fremantle, WA

TRANSPORTATION AND PACKAGING

In bulk via road train.

USE

The notified chemical is used as feedstock (intermediate) for the industrial manufacture of titanium products. It is used in the production of titanium chloride (TiCl₄) which is then used to produce TiO₂ pigments and (ferro)titanium alloys. The titanium chloride manufactured from the notified chemical is then oxidised via a patented process to produce TiO₂ pigment or titanium alloys. The final product has many end uses as a pigment, including coatings and plastics. The products then undergo finishing process prior to bagging and sale. Finished products are mainly intended for export.

OPERATION DESCRIPTION

The notified chemical will be unloaded from trucks and hoppers and transferred by belt conveyors and bucket elevators to cross belts and from there to storage bins. The notified chemical and other feedstock chemicals are pneumatically transferred to the reactors.

The process involves the reaction of high Ti content feedstock (including the notified chemical and other ores such as rutile, synthetic rutile, leucoxene) with chlorine and petroleum coke in fluidised bed reactors to produce titanium tetrachloride which is purified by fractional condensation and distillation. The resultant TiCl₄ is oxidised via a patented process to produce TiO₂ pigment. This pigment then undergoes a finishing process prior to bagging and sale (mainly for exportation).

All process runoff water, waste water and liquid discharges from the plant are treated in the effluent treatment plant. After neutralisation of the liquid wastes, the wastewater is diverted to a primary thickener, where added flocculent assists with settling solids, and then to a polishing thickener. Overflow of liquid is transferred to lined effluent ponds, while underflow is pressed into solid waste. Further solids are removed through settling that occurs in the effluent ponds and are removed. Water is recycled for low grade applications on site while excess waste water is pumped to ocean outfall if it meets quality conditions. Solid process wastes are collected and temporarily stored (in built-for-purpose storage) on site prior to transport for disposal offsite by a licenced contractor.

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	2	20
Process Operators/ Bagging Unit Operator	12	180
Maintainers	2	80

EXPOSURE DETAILS

The material is inert and granular in nature. Dust may be generated (airborne contaminants) during transfer processes and when converted to its final product form (TiO₂ pigment).

The notified chemical is used as feedstock in an enclosed industrial process. The notifier states that workers are not directly exposed to the notified chemical during smelting. Exposure to workers may occur during transport, transfer and preparation of the final product (bagging), maintenance of associated equipment or inadvertent spillage or release (e.g. generation of dust). The notifier states that environmental management systems are certified to ISO14001 (ISO, 2004).

Transport, handling and storage

Workers involved in the transport, transfer and loading/unloading of the material may be exposed during the transfer of material between transport equipment and during the change of storage locations. The main route of exposure will be via inhalation and dermal contact of particles caused by the generation of dust. Transfer activities are generally of short duration and occur episodically. Transfer from the ship hold to storage will occur over a matter of hours, where workers will observe from a removed location. The loading of trucks from storage and unloading at the processing site will occur rapidly and workers will remain within the transport vehicle. Transfer and transport equipment will generally be enclosed with dust control/extraction facilities. Feeding the material into the processing chain may occur using a front end loader, minimising direct worker exposure. The notifier states that good general ventilation should be sufficient to control worker exposure to airborne contaminants, but other stated engineering controls include the use of product enclosures and local exhaust ventilation. The notifier states that PPE will be used, such as eye protection, respiratory protection and industrial clothing, where required. Monitoring of dust exposure (personal dust) and generation (environmental dust) will be periodically undertaken.

Processing to TiO₂

Processing will generally be undertaken in enclosed industrial set up. Production operators and other personnel will not generally be directly exposed to the material except during checking (quality control step) and maintenance of the equipment. During such tasks, equipment will be isolated. The notifier states exposure to the notified chemical will be minimised through the utilisation of PPE.

6.1.2. Public Exposure

The notified chemical is intended for use as feedstock for the industrial manufacture of titanium products and is not intended for use by the public. Public exposure is expected to occur only in the event of a transport accident or dust drift.

Measures to minimise public exposure to the notified chemical include avoiding creating dusty conditions on the formulation site and prevention of wind dispersal of dust and other spilled material. Therefore, given the proposed use pattern, public exposure is not expected.

6.2. Human Health Effects Assessment

Toxicological data were submitted for the notified chemical and related analogue, TiO₂ (pigment grade). 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
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation –Maximisation test.	no evidence of sensitisation
Rat, Carcinogenicity via oral route – 2 years*	NOEL 2,400 mg/kg bw NOAEL 3,500 mg/kg bw

* Study conducted on the final product TiO₂/dioxotitanium (containing the notified chemical)

Toxicokinetics, metabolism and distribution.

The notified chemical is a water insoluble solid; absorption through the skin and gastro-intestinal membranes is not expected. The possible toxicokinetics of the notified chemical when exposed to the human body was tested in a quantitative *in-vitro* bioaccessibility assay. The assay tested nine different metal ions (including Ti, the ion of interest) which were exposed to synthetic biological media of different pH and chemical composition. The test media were chosen in order to simulate relevant inhalation scenarios where the different Ti slags may enter the human body through inhalation and, by subsequent ingestion of inhaled particles, these are translocated to the gastro-intestinal tract. Overall the released concentrations of Ti ions from the notified chemical slags were low. The data suggested Ti release was influenced by the composition and pH of the test media, where released concentrations increased with solution acidity. As the lung interstitial fluid, lung cells and blood serum are more alkaline, it was concluded that when those organs are exposed to the notified chemical, free Ti concentrations will be reduced.

Acute toxicity.

The notified chemical was of low acute oral toxicity in a study in rats.

No acute dermal toxicity data were provided for the notified chemical. However the notifier states that absorption from dermal exposure is unlikely due to the physicochemical properties of the notified chemical. Forms of TiO₂, the main component of the notified chemical, which are used in cosmetics as colorants or UV filters, were not toxic by the dermal route in rabbits (SCCS, 2000). The SCCS opinion concluded that ‘the toxicological profile of this material does not give rise to concern in human use, since the substance is not absorbed through the skin’.

No acute inhalation toxicity data were provided for the notified chemical as a suitable atmosphere could not be experimentally generated (according to OECD TG 436); it precipitated instead. This was stated to be caused by the particle size and low vapour pressure of the notified chemical.

Occupational inhalation toxicity studies conducted for TiO₂ showed no systemic effects in humans. A long-term derived no-effect level (DNEL) of 10 mg/m³ was calculated for local effects (non-neoplastic lung effects) in workers exposed via inhalation to pigment grade TiO₂ (the analogue chemical). The respirable fraction of pigment grade TiO₂ is significantly higher than the notified chemical.

Irritation and sensitisation.

Animal studies showed the notified chemical to be non-irritating via both the dermal and ocular routes. No human data was available for skin or eye irritation.

The notified chemical at concentrations up to 50% in a guinea pig maximisation test showed no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation.

Repeated dose toxicity.

Repeated dose toxicity studies for the analogue chemical were summarised in a chemical safety report (Rio Tinto, 2010). In a 28-day study, rats were exposed to the analogue chemical by gavage. The NOEL was established at 24,000 mg/kg bw/day. A bioassay testing carcinogenicity in rats was considered the key study for repeated dose toxicity via the oral route (NCI, 1979). The study was conducted on the end product TiO₂ (containing the notified chemical) at 3,500 mg/kg bw/day. No signs of toxicity were seen during the study and no tumours occurred in dosed groups at incidences that were significantly higher than those for the corresponding control groups. The only clinical symptoms noted were white faeces in some rats. Based on the lack of any observed adverse effects, the NOAEL was established for TiO₂ at 3,500 mg/kg bw/day.

11 repeated dose inhalation (whole body) studies were summarised in the chemical safety report (Rio Tinto, 2010). Rats were exposed for periods between 28 days and 24 months. The 24-month studies were combined repeated dose and carcinogenicity studies.

In one study where the analogue chemical was of respirable size (95% of the particles were < 10 µm, average size 1.5 µm) animal survival was comparable to controls and did not have any compound-related clinical signs of toxicity up to the maximum dose of 250 mg/m³ (6 hours a day, 5 days a week). Histopathological evaluation showed a significant dose related increase over controls in the incidence of rhinitis, squamous metaplasia, and tracheitis. The incidence of benign lung tumours was significantly increased in the rats exposed in the high dose group.

In one study where the analogue chemical was of sub-pigmentary grade, the analogue chemical had a particle size between 15 and 40 nm with a MMAD of 0.8 µm (agglomerates). The mean lifetime of rats exposed to 10 mg/m³ for 24 months was significantly shortened with 90% mortality at the end of the experiment. Wet lung weights increased substantially during exposure and alveolar lung clearance rates were significantly compromised after three months of exposure. A three month recovery period following 18 months of exposure showed no reversibility of the damage.

Mutagenicity/Genotoxicity.

No studies for mutagenicity and genotoxicity were conducted on the notified chemical. However, study data are available for the end product, TiO₂. TiO₂ was not mutagenic in a bacterial reverse mutation study (in the presence or absence of metabolic activation) and was not clastogenic in an *in vitro* mammalian chromosome aberration test. *In vitro* genotoxicity studies showed that TiO₂ did not induce cytotoxicity in mouse lymphoma L5178Y cells in a mammalian cell gene mutation assay. Test results for TiO₂ were negative in two out of two *in vivo* and negative in nine out of 11 *in vitro* tests.

Carcinogenicity.

The chemical safety report (Rio Tinto, 2010) for the notified chemical states that TiO₂ was classified as a possible carcinogen (IARC 2B) via inhalation based on animal and lung particle overloading studies. It was not a carcinogen by the oral route. The specie (rats) selected for the studies was shown to be uniquely susceptible to the development of tumours due to chronic inflammation from lung particle overloading at high doses.

There were eight exposure-related studies in humans. The IARC working group concluded 'that the studies do not suggest an association between occupational exposure to the analogue chemical titanium dioxide and carcinogenicity. The epidemiological studies on the analogue chemical provide inadequate evidence of carcinogenicity. No causative link between titanium dioxide exposure and carcinogenicity in humans has been demonstrated.'

Health hazard classification

Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Transportation, handling and storage

Transport and handling workers may be exposed to the notified chemical via the dermal, ocular and inhalation routes. This is expected to occur during transfer of the material containing the notified chemical from transport tanks to mixing vessels to storage containers and during general maintenance operations. However, these processes are undertaken episodically with short duration and are expected to be conducted in enclosed areas (such as where the worker remains inside the vehicle) and utilising exhaust ventilation.

End Use

Process operators and bagging workers may be exposed to the notified chemical via the dermal, ocular and inhalation routes. Exposure is expected to be minimised during these processes through the use of engineering controls (enclosed operations, exhaust ventilation, automated operations) and the use of PPE.

The main route of exposure for all workers is by inhalation. The generation of dusts during transport, handling and bagging operations are the main processes where inhalation exposure may occur. The notified chemical has a larger particle size than the processed TiO₂ pigment, and much smaller proportion of respirable particles. The inhalable fraction of the notified chemical is expected to be cleared through the mucociliary action of the lungs.

Exposure is expected to be minimised by the use of adequate local ventilation systems and respiratory protection. Monitoring of dust generation and exposure is to be periodically undertaken.

Under the proposed occupational settings to minimise worker exposure, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

The notified chemical is intended for use in industrial settings by trained workers. The public may only be exposed to the notified chemical in the unlikely event of an accident during transport. Therefore, when used in the proposed manner, the risk to public health from the notified chemical 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 processed to produce TiO₂ pigment. This process involves processing the notified chemical to remove impurities.

All process runoff water, waste water, and liquid discharges from the plant are directed to the Effluent Treatment Plant (EFT). This is then directed to a thickener where flocculent is added to assist with solids settling. Solid waste containing the notified chemical from the filters is expected to be disposed of to landfill. Clarified water is recycled for low grade applications in the plant and excess water is pumped to an ocean outfall. Water not meeting the quality standard is diverted for further treatment.

Approximately 44,000 tonnes (22% of 200,000 tonnes) of the import volume is expected to be disposed of to landfill or expected to be stored at site for future processing.

RELEASE OF CHEMICAL FROM USE

The notified chemical is converted to the final product TiO₂ pigment which is automatically bagged into quantities ranging from 25 kg to 1,000 kg. Therefore, release from this activity is not expected to be significant.

RELEASE OF CHEMICAL FROM DISPOSAL

The volume of the notified chemical lost to the environment via accidental spills, leaks, authorised discharges (includes dust or gaseous emissions to atmosphere from the process via emissions control equipment) is expected to be 40 tonnes (<0.02% of 200,000 tonnes) of the import volume. This is expected to be handled by physical containment, collection and subsequent disposal to landfill.

7.1.2. Environmental Fate

In effluent treatment plants > 95% of the notified chemical is expected to settle to sludge due to its negligible water solubility. Any notified chemical released to surface water is also expected to partition to sediment based on its limited water solubility. It is assumed that notified chemical derived titanium and the ambient environmental titanium have the same fate and distribution level. The Bioconcentration Factor (BCF) of environmental titanium is 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.

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 when used in mining processes. A Predicted Environmental Concentration (PEC) has therefore 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>
Fish Toxicity	EC50 (96 h) >100 mg/L WAF	Not harmful to fish

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
Sediment Reworker Toxicity	NOEC (28 d) ≥ 10%	Not harmful to sediment dwellers
Terrestrial Organism Toxicity	NOEC (28 d) 0.1%	Not harmful to soil macro-organisms
Inhibition of Bacterial Respiration	EC50 >100 mg/L	Not expected to inhibit bacteria.
Seedling Emergence & growth	NOEC (20 d) ≥ 10 mg/L	Not expected to inhibit seedling emergence and growth.

Water Accommodated Fraction (WAF)

Classification should be based only on toxic responses observed in the soluble range. The Transformation/Dissolution study conducted on notified chemical indicated that, within the limits of experimental error and analytical capabilities, titanium remained refractory to the conditions of the method, not dissolving from any of the samples. These data would be sufficient to propose a null hazard classification proposal for the notified chemical. The ecotoxicity endpoints for the notified chemical are much higher than its 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 ($RQ = PEC/PNEC$) has not been calculated. The notified chemical is not considered to be harmful to environmental organisms. Moreover, after processing the notified chemical, the waste generated will be sent to landfill where due to its negligible water solubility and complex inorganic structure is not expected to be mobile or bioavailable. The notified chemical is not expected to be bioaccumulative in the environment. Therefore, based on the 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	1550–1850 °C
Method	OECD TG 102 Melting Point/Melting Range. Council Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	The test item was found to have no melting point at atmospheric pressure in the temperature range of 25–600°C
Test Facility	Siemens (2008a)
Boiling Point	>600 °C at 101.3 kPa
Method	OECD TG 103 Boiling Point. Council Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	The test item was found to have no boiling point at atmospheric pressure in the temperature range of 25–600°C
Test Facility	Siemens (2008b)
Relative Density	1.9–2.5 kg/m ³ at 21.5–24.3 °C
Method	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	D4R values determined for each Ti-slag sample. Results compared to water at 4 °C
Test Facility	EBRC (2007)
Water Transformation/Dissolution Study	≤ 19 µg/L for various metal species
Method	OECD No 29 Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media.
Remarks	100 mg of titanium slag samples (5) were mixed with 1,000 mL of reconstituted water with a pH of 6.0 and hardness of 250 mg/L expressed as CaCO ₃ . The mixtures were stirred for 24 hours. The slag samples were analysed for 12 metals namely Al, Co, Cu, Cr, Fe, Mn, Mo, Nb, Ti, V and Zn. The five titania slags were stable under the experimental conditions. Data indicated that only Fe, Mn, and V among the 12 metals dissolved to any significant extent. Over 24 hour, the slags released Mn in the range 2–7 µg/L and Fe 8–26 µg/L and V at a maximum of 3.5 µg/L respectively. Within the limits of experimental error and analytical capabilities, the other metals remained refractory to the conditions of the method, none dissolving from any of the titania slags. It is thus concluded that the notified chemical is insoluble in water.
Test Facility	CANMET (2007)

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

TEST SUBSTANCE	Notified chemical – Exxaro Sulphate Slag, UGI (Upgraded Ilmenite)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. Directive 2004/73/EC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/ Crl:CD Sprague-Dawley
Vehicle	0.8% aq. hydroxypropylmethylcellulose
Remarks - Method	GLP certificate. No significant protocol deviations. A single oral dose of 2,000 mg/kg bw was administered to test animals. The rats were observed for deaths or overt signs of toxicity at 6 and 24 hours and 7 and 14 days after dosing.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3F	2,000	0/3
2	3F	2,000	0/3

LD50	>2,000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were noted.
Effects in Organs	No pathological abnormalities were noted at necropsy.
Remarks - Results	All animals survived and showed the expected weight gain during the study. The study authors have suggested no symbol or risk phrase is required according to EU labelling regulations.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
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TEST FACILITY	LPT (2008a)
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B.2. Irritation – skin

TEST SUBSTANCE	Notified chemical – Exxaro Sulphate Slag, UGI (Upgraded Ilmenite)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/Himalayan
Number of Animals	3 M
Vehicle	None – solid formulation used
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP certificate. No significant protocol deviations. Single 4-hour semi-occlusive application of 500 mg of the test material to intact skin. The rabbits were observed for deaths or overt signs of toxicity at 1, 24, 48 and 72 hours after patch removal. The Draize scale (0–4) was used to grade the irritancy potential of the skin reaction.

RESULTS

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

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

Remarks - Results	No skin reactions were observed for the test animals. There was no systemic intolerance reactions noted. Additional observations after 72 hours post patch removal to assess the reversibility of skin reactions were waived, as none of the test animals showed any significant test-item related lesions at the preceding time point observations.
CONCLUSION	The notified chemical is non-irritating to the skin under the test conditions.
TEST FACILITY	LPT (2008)

B.3. Irritation – eye

TEST SUBSTANCE	Notified chemical – Exxaro Sulphate Slag, UGI (Upgraded Ilmenite)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/Himalayan
Number of Animals	3 M
Observation Period	72 hours
Remarks - Method	GLP certificate. Single ocular instillation into the right eye of the test animals with 100 mg of the test material. Observations were taken at 1, 24, 48 and 72 hours post-dosing. The Draize Scoring system was used to grade the eye reaction observations.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0.25	0.25	0.25	1	1 hour	0
<i>Conjunctiva: chemosis</i>	0	0	0	0	0	0
<i>Corneal opacity</i>	0	0	0	0	0	0
<i>Iridial inflammation</i>	0	0	0	0	0	0

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

Remarks - Results	Grade 1 conjunctival redness and secretion was observed in all animals 1 hour after instillation. The corneae and the irises were not affected by instillation of the test item. The fluorescein test performed 24 hours after instillation did not reveal any changes. There were no systemic intolerance reactions.
CONCLUSION	The notified chemical is non-irritating to the eye under the conditions of the test.
TEST FACILITY	LPT (2008)

B.4. Skin sensitisation

TEST SUBSTANCE	Notified chemical – Exxaro Sulphate Slag, UGI (Upgraded Ilmenite)	
METHOD	OECD TG 406 Skin Sensitisation - Magnusson & Kligman Maximisation. EC Directive 96/54/EC B.6 Skin Sensitisation - Magnusson & Kligman Maximisation.	
Species/Strain	Guinea pig/Dunkin-Hartley	
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 0.1 mL topical: 2 mL	
MAIN STUDY		
Number of Animals	Test Group: 10M	Control Group: 5M
INDUCTION PHASE	Induction Concentration: intradermal: 0.5% w/w in water topical: 50% w/w water	
Signs of Irritation	No skin reactions were observed at any concentration	
CHALLENGE PHASE		
Single challenge	topical: 50% in water	
Remarks - Method	GLP certificate. The positive control Benzocaine in 40% ethanolic 0.9% NaCl solution data was taken from a historical background study performed in 2007. The vehicle control, Freund's complete adjuvant (FCA) diluted with 0.9% NaCl was used in tandem with the test substance. During the 1 st induction stage no changes were detected. During the 2 nd induction stage, the test material was found to be non-irritating.	

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after Challenge:</i>
<i>Test Group</i>	50%	0/10
<i>Control Group</i>	Benzocaine	20/20
	FCA	0/5

Remarks - Results	During the challenge phase, the test material did not cause any skin irritation in any test animal. The positive control caused a sensitising reaction in the form of discrete or patchy erythema in all exposed animals No signs of systemic toxicity were observed in the test animals. No skin reactions were noted at the rechallenge sites of the test and control group animals. The increases in test group animal body weight were within the range of the vehicle control group during the experiment. Behaviour of the animals remained unchanged. The controls achieved values within the expected range, confirming the validity of the study.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	LPT (2008)

B.5. Quantitative in-vitro Bio-accessibility

TEST SUBSTANCE	Notified chemical – from 9 production sources. Analogue chemical.
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METHOD	In-house method based on peer-reviewed literature.
Method	<p>Study was conducted on released metal ions from nine different Ti-slugs when exposed to synthetic biological media on different pH and chemical composition. For comparison, a TiO₂ pigment was analysed in parallel.</p> <p>Triplicate slag samples were prepared for exposure in four different test media in TPX Nalge jars and incubated in Merck incubator dark conditions for 2 (to test for artificial gastric fluid digestion) and 24 hours (to compare with metal ion release/ dissolution data). The four different test media (Phosphate-buffered saline, Gamble's solution, artificial lysosomal fluid and artificial gastric fluid) were used to screen at relevant pH levels between 1.5 and 7.5. The media were chosen in order to simulate relevant inhalation scenarios where the different Ti test items may enter the human body through inhalation and by ingestion of inhaled particles that are translocated to the gastro-intestinal tract.</p> <p>With Ti, the main element releases of concern included Fe, V, Mg, Mn, Cr and Cu.</p>
Remarks	<p>The released concentrations of Ti ions from all test items were generally low. The Ti release was influenced by the composition and pH of the test media. The released concentrations increased with solution acidity.</p> <p>Release of iron occurred from most test items, except KRO TiO₂ and QIT CL at a very low concentration for most slags for all media investigated.</p> <p>Relevant release of magnesium could only be observed in PBS and GST. Due to a high intrinsic magnesium content of GMB and ALF, no further evaluation of magnesium release was performed.</p> <p>Copper and chromium are not released to any relevant extent from any of the test items, except for the EXX SO slag in GMB after 24 hours of exposure.</p>
Test Facility	Royal Institute of Technology, Sweden (2007)

B.6. Chronic toxicity/carcinogenicity

TEST SUBSTANCE	Titanium Dioxide
METHOD	Bioassay of possible carcinogenicity
Species/Strain	Rats/Fischer 344 and Mice/B6C3F1
Route of Administration	Oral – diet
Exposure Information	Total exposure: 24 months Dose regimen: 7 days per week;
Vehicle	2% corn oil
Remarks - Method	

RESULTS		Rats	
Group	Number and Sex of Animals	Dose/Concentration ppm	Mortality
			<i>M/F</i>
1	50 per sex	0	19/50
2	50 per sex	25,000	13/50
3	50 per sex	50,000	14/50
<i>Mice</i>			
Group	Number and Sex of Animals	Dose/Concentration ppm	Mortality
			<i>M/F</i>
1	50 per sex	0	3/50
2	50 per sex	25,000	1/50
3	50 per sex	50,000	1/50

Mortality and Time to Death

Survival of rats of both genders and male mice at the end of the bioassay was not affected by the test item. However the survival of the high-dose female mice was shorter than that of the low-dose and control groups.

Clinical Observations

Administration of the test material did not have an appreciable effect on the mean body weights of the test

animals. Clinical signs observed in the dosed groups included alopecia, sores and lacrimating, protruding eyes. However these signs were generally comparable to those of the control group. All animals in the dosed groups were noted to have white faeces.

Effects in Organs – General

In male rats, pheochromocytomas of the adrenal medulla and fibromas of the subcutaneous tissue were observed with slightly greater frequency in dosed groups, however the number of neoplasms was compatible with incidences of these tumours in historical-control rats of this age and strain.

In female rats, endometrial stromal polyps were observed more frequently in dosed groups than in control groups, but the incidence of lesions is comparable with that in historical controls. Hence these lesions were not considered by the study authors to be test-related.

Inflammatory, degenerative and hyperplastic lesions that occurred were similar in number and kind to naturally occurring lesions common to aged Fischer 344 rats.

Effects in Organs – Tumours

In female rats, C-cell adenomas of the thyroid occurred at incidences that were dose related, but the study authors did not deem the incidences statistically significant enough to meet the Bonferroni criterion. Thus these tumours of the thyroid were not considered to be test related.

Remarks – Results

The test item was not found to affect the nutritional quality of the diet. No neoplastic effects were noted during the study. There was deemed no significant difference in the number of dosed rats and mice at risk of developing late-appearing tumours, compared to the control animals.

CONCLUSION

Based on the lack of observed Adverse Effects at the dose, the NO(A)EL was determined to be 35,000 mg/kg bw/day under the conditions tested. As white faeces were seen in the highest dose group, the NOEL was set at 24,000 mg/kg bw/day.

TEST FACILITY: National Cancer Institute (1997)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	Zebra fish (<i>Danio rerio</i>)
Exposure Period	96 hours
Auxiliary Solvent	Not reported
Water Hardness	250 mg/L CaCO ₃
Analytical Monitoring	Not reported
Remarks – Method	The test was conducted according to the guidelines above. 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 (200 mg) to the aqueous test medium (2 L). The test sample was stirred for 7 days in an incubator (22 °C, 100 rpm, dark). 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

<i>Nominal Concentration mg/L(WAF)</i>	<i>Number of Fish</i>	<i>Mortality</i>			
		<i>24 h</i>	<i>48 h</i>	<i>72 h</i>	<i>96 h</i>
Control	7	0	0	0	0
100	7	0	0	0	0

EL50 >100 mg/L (WAF) at 96 hours.

NOEL Not reported

Remarks – Results All validity criteria for the test were satisfied. The results are based on the nominal concentrations.

CONCLUSION The notified chemical is not harmful to fish

TEST FACILITY Arcadis (2009a)

C.2.2. 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	Not reported
Analytical Monitoring	None reported
Remarks - Method	The test was conducted according to the guidelines above. 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 mg) to the aqueous test medium (1 L). The test sample was stirred for 7 days (250 rpm). 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

<i>Concentration mg/L (WAF)</i>	<i>Number of D. magna</i>	<i>Number Immobilised</i>	
		<i>24 h</i>	<i>48 h</i>
Control	30	0	0
100	30	0	0

EL50	> 100 mg/L at 48 hours
NOEL	Not reported
Remarks - Results	All validity criteria for the test were satisfied. The results are based on the nominal concentrations.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrates
TEST FACILITY	Arcadis (2009b)

C.2.3. 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
Auxiliary Solvent	Not reported
Water Hardness	25 mg CaCO ₃ /L
Analytical Monitoring	Not reported
Remarks - Method	The test was conducted according to the guidelines above. 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 mg) to the aqueous test medium (1 L). The test sample was stirred for 7 days (250 rpm). 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	
EL50	> 100 mg/L at 72 hours
NOEL	Not reported
Remarks - Results	All validity criteria for the test were satisfied. The results are based on the nominal concentrations.
CONCLUSION	The notified chemical is not harmful to algae
TEST FACILITY	Arcadis (2009c)

C.2.4. Plant Growth Test on Summer Barley and Lettuce

TEST SUBSTANCE	Notified chemical
METHOD	ISO 11269-2 protocol for growth test and ISO 14238 protocol for nitrification test.
Exposure period	20 days
Remarks - Method	An approximate amount of dry soil was mixed with notified chemical (0, 0.03, 0.1, 1, 3 and 10%) and mixed in a concrete mixer to final amount of 4,292 g dry matter. This mixture was homogenised for 5 minutes. All treated soils were moistened to 18.5% by adding deionised water and mixed manually. A 144 g sub sample was set apart for nitrification test. The remaining soil was immediately moistened to 23.5% moisture and mixed manually for the plant growth test. 10 seeds of both species were sown on top of the soil (lettuce) and 0.5–1 cm under the soil surface (barley).
RESULTS	
NOEC (barley and lettuce)	Emergence ≥ 10%. Shoot yield > 10%.
LOEC (barley and lettuce)	Emergence ≥ 10%. Shoot yield > 10%.
Remarks - Results	No effect was observed on the emergence and growth of both barley and lettuce plants at all concentrations tested. Therefore, an unbounded NOEC and LOEC higher than the highest test concentration (10%) were reported.
CONCLUSION	The notified chemical is not harmful to plant growth.
TEST FACILITY	Arcadis (2008)

C.2.5. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical (Exxaro Cl and RBM Cl)
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: Control, Water Accommodated Fraction (WAF) 100 mg/L
Remarks – Method	The test was conducted according to the guidelines above. No significant deviations from the test guidelines were reported.
<p>The test solution was prepared as a Water Accommodated Fraction (WAF). The WAF solution was prepared by adding test substance (200 mg) to the aqueous test medium (2 L). The test sample was stirred for 7 days in an incubator (22 °C, 200 rpm, dark). 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.</p>	
RESULTS	
IC50	>100 mg/L
NOEC	100 mg/L
Remarks – Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration.
TEST FACILITY	Arcadis (2009e,g,f)

C.2.6. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical (Exxaro Cl)
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: Control, Water Accommodated Fraction (WAF) 112 mg/L
Remarks – Method	The test was conducted according to the guidelines above. No significant deviations from the test guidelines were reported.
<p>The test solution was prepared as a Water Accommodated Fraction (WAF). The WAF solution was prepared by adding test substance (112 mg) to the aqueous test medium (1 L). The test sample was stirred for 7 days in an incubator (22 °C, 200 rpm, dark). 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.</p>	
RESULTS	
IC50	>112 mg/L
NOEC	112 mg/L
Remarks – Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration.
TEST FACILITY	Vito (2010a)

C.2.7. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical (RBM Cl)
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: Control, Water Accommodated Fraction (WAF) 111.8 mg/L
Remarks – Method	The test was conducted according to the guidelines above. No significant deviations from the test guidelines were reported.
<p>The test solution was prepared as a Water Accommodated Fraction (WAF). The WAF solution was prepared by adding test substance (111.8 mg) to the aqueous test medium (1 L). The test sample was stirred for 7 days in an incubator (22 °C, 200 rpm, dark). The mixture was</p>	

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	
IC50	>111.8 mg/L
NOEC	111.8 mg/L
Remarks – Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration.
TEST FACILITY	Vito (2010b)

C.2.8. Chronic Amphipod Survival and Growth Test

TEST SUBSTANCE	Notified chemical
METHOD	ASTM E1706 guideline.
Species	<i>Hyalella azteca</i>
Exposure period	28 days
Remarks - Method	The test was performed in a thermostatically controlled room at 25 °C. Hardness and salinity were not measured. The test was performed with 5 different concentrations: 0.1, 0.3, 1, 3 and 10% w/w of the notified chemical in water overlaying the sediment.
RESULTS	
NOEC	≥ 10% w/w at 28 days.
Remarks - Results	The growth was statistically determined by the dunnet test.
CONCLUSION	The notified chemical is not expected to be harmful to <i>Hyalella azteca</i> at concentrations ≤ 10% w/w.
TEST FACILITY	Arcadis (2009h)

C.2.9. Chronic Soil Macroorganism Survival and Reproduction Test

TEST SUBSTANCE	Notified chemical
METHOD	ISO 11267 guideline.
Species	<i>Folsomia candida</i>
Exposure period	28 days
Remarks - Method	A preliminary chronic soil testing was performed using maximum concentration of 10% of the notified chemical.
	The definitive tests were performed with 5 different concentrations: 0.1, 0.3, 1, 3 and 10% w/w of the notified chemical.
RESULTS	
NOEC	0.1%.w/w at 28 days
Remarks - Results	Due to the heterogeneous nature of the notified chemical, no firm conclusion on the terrestrial toxicity could be drawn. No clear dose-response curve could be derived from the results of the repeated definitive tests.
CONCLUSION	The notified chemical is not expected to be harmful to <i>Folsomia candida</i> at concentrations ≤ 10% w/w.
TEST FACILITY	Arcadis (2009i)

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