This project is implemented through the CENTRAL EUROPE Programme co-financed by the ERDF

Material Safety Data Sheet

DATE: 03/12/13

1. Identification of substance and of the company/undertaking

1.1 Product identifier

Substance Name: suspension of ultrafine titanium dioxide; rutile

EC No.: (EINECS) 236-675-5

REACH Registration No.: NA

CAS No.: 13463-67-7

1.2 Relevant identified uses of the substance and uses advised against

Relevant identified uses: Use of the suspension to formulate UV protective, transparent coatings, additives for plastic and additives for cosmetic products.

Coatings and paints (PC9a), Paper and board dye, finishing and impregnation products: including bleaches and other processing aids (PC26), Cosmetics, personal care products (PC39), Formulation of preparations (ERC2)

Uses advised against: Consumer use (SU21)

Reasons why uses advised against: The use of ultrafine titanium dioxide by the general public is advised against due to the risk of human and environmental exposure (it is not biodegradable).

1.3 Details of the supplier of the Safety Data Sheet

Manufacturer/Supplier: NA

Street address/P.O. Box: NA

Country ID/Postcode/Place: NA

Telephone number: NA

Email address of competent person for the SDS: NA

National Contact: NA

1.4 Emergency telephone number

Opening hours:

2 Hazards identification

2.1 Classification of the substance

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]

Titanium oxide as such is not classified.

2.1.2 Classification according to Directive 67/548/EEC
NA
2.1.3 Additional information
/
2.2 Label elements
Labelling according to Regulation (EC) No 1272/2008 [CLP]
Hazard pictograms: /

Signal word:
Signal word: GHS07
Classification: R52-53.

Hazard statements: H303, H313, H333
H303: May be harmful if swallowed
H313: May be harmful in contact with skin
H333: May be harmful if inhaled

2.2 Other hazards

3. Composition/information on ingredients
3.1 Substances

Name	**Index number in CLP Annex VI**	**Weight % content (or range)**
TiO2	**N.A.**	**Minimum 15%**

3.2 Mixtures

4 First aid measures
4.1 Description of first aid measures
General notes:

Following inhalation: The product is suspension (wet) so there is no danger of inhalation.
In the case of an accident consult a doctor.

Following skin contact: Wash with water and soap and rinse thoroughly. If needed seek for medical advice.

Following eye contact: Immediately rinse opened eye for at least 15 minutes under running water. If needed

seek for medical advice and bring safety data sheet with you.

Following ingestion: Rinse mouth with water. If needed seek medical treatment.

Self-protection of the first aider: -

4.2 Most important symptoms and effects, both acute and delayed
Not known

4.3 Indication of any immediate medical attention and special treatment needed
Not known

5 Fire fighting measures

5.1 Extinguishing media:
Suitable extinguishing media: The product is not flammable. In the case that it is involved in a fire, all extinguishing media can be used.

Unsuitable extinguishing media: Not known

5.2 Special hazards arising from the substance or mixture:
Hazardous combustion products: Not known
5.3 Advice for fire-fighters: Additional protection is not needed. Wear protection that corresponds to the general situation of fire.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:
Wear protective equipment as are gloves and glasses.

6.1.1 For non-emergency personnel:
Wear protective equipment as are gloves and glasses.

Measures for environmental protection:
The product is inert and does not present direct hazard to the environment. Do not allow material to be released to the environment without proper governmental permits.
Measures for cleaning/collecting: Pick up mechanically. The product is neutral and decontamination measures are not needed. All inert sorbents can be used. Wear protective equipment as are gloves and glasses. Inappropriate cleaning and retention measures are not known.
Additional information:
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

7.1 Precaution for safe handling:

Protective measures:

Measures to prevent fire: No special measures required.

Measures to prevent aerosol and dust generation:

Measures to protect the environment: The product should not be discharged into drains and surface waters.

Advice on general occupational hygiene:

Keep container tightly sealed.
Store in wet form in cool, dry place in closed containers.
No special precautions are necessary if used correctly.

7.2 Conditions for safe storage, including any incompatibilities:

Technical measures and storage conditions:

The product is inert.

Packaging materials:

Requirements for storage rooms and vessels:

No special requirements.

Storage class:

Further information on storage conditions

Keep container tightly sealed.
Store in cool, dry conditions in well-sealed containers.

8 Exposure controls and personal protection

8.1 Control parameters

- Nano TiO2 (rutile) (IARC Monographs Vol. 93)
  mg/m^3
  USA
  ACGIH (TLV)TWA 10 (not classifiable as a human carcinogen)
  OSHA (PEL) TWA 15 (total dust)
  Austria TWA-ACC 6

Belgium TWA-ACC 10
China TWA 8 (total dust)
short term exp.limit 10
Canada TWA 3-10
Denmark TWA 6
Finland TWA 10
France TWA 10
Germany MAK 1,5
Netherlands TWA-ACC 10 (inhalable dust)/5 (respirable dust)
Norway TWA 5
Sweden TWA 5 (total dust)
Switzerland TWA 3
United Kingdom TWA 4 (respirable dust)

Occupational exposure limits values (http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx):

Substance	Titanium dioxide
CAS No.	13463-67-7

	Limit value - Eight hours		Limit value - Short term	
	ppm	mg/m³	ppm	mg/m³
Australia		10 (1)		
Austria				
Belgium		10		
Canada - Ontario		10		
Canada - Québec		10		
Denmark		6 total dust		12 total dust
European Union				
France		11 inhalable aerosol		
Germany (AGS)				0,8 inhalable aerosol (1)
Germany (DFG)				0,8 inhalable aerosol

Hungary			0,4
Italy			
Japan			
Latvia		10	
New Zealand		10 (1)	
Poland		10	30
Singapore		10	
South Korea		10	
Spain		10 inhalable aerosol	
Sweden		5 inhalable aerosol	
Switzerland		3 respirable aerosol	
The Netherlands			
USA - NIOSH			
USA - OSHA		15 total dust	
United Kingdom		10 inhalable aerosol	
		4 respirable aerosol	

Remarks	
Australia	(1) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.
New Zealand	(1) The value for inhalable dust containing no asbestos and less than 1% free silica.

Information on monitoring process:

N.R:

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Substance/mixture related measures to prevent exposure during identified uses: NA

Structural measures to prevent exposure: NA

Organisational measures to prevent exposure: NA

Technical measures to prevent exposure: Properly operating chemical fume hood designed for hazardous chemicals and having an average face velocity of at least 100 feet per minute. Filtering cabinet connected to ventilation system to the outside. General ventilation of laboratory environment.

8.2.2 Personal protection equipment: The usual precautionary measures for handling chemicals should be followed. Keep away from foodstuffs, beverages and feed. Remove all soiled and contaminated clothing immediately. Wash hands before breaks and at the end of work.

8.2.2.1 Eye and face protection: Safety glasses

8.2.2.2 Skin protection: Protective work clothing

TiO2 in pigmentary and ultrafine forms is used in cosmetics applications (e.g. lipsticks, make-up products and sunscreens). It has been conclusively demonstrated that TiO2 is safe for use in sunscreen products to protect skin from harmful effects of solar UV radiation. Comprehensive in vivo and in vitro dermal penetration studies have been performed (7).

8.2.2.3 Hand protection: Impervious gloves

Other skin protection:

8.2.2.3 Respiratory protection: /
For powders: Use suitable respirator when high concentrations are present. Consumer exposure to TiO2 dust is presumed to be very low because TiO2 is typically incorporated into a product matrix where it is tightly bound such as in paints or plastics. Thus, inhalation exposure is not considered as relevant for the general public (7).

8.2.2.4 Thermal hazards:

8.2.3 Environmental exposure controls:

Substance/mixture related measures to prevent exposure during identified uses: NA

Structural measures to prevent exposure: NA

Organisational measures to prevent exposure: NA

Technical measures to prevent exposure: Filtered ventilated air before release to the outside

9 Physical and chemical properties:

9.1 Information on basic physical and chemical properties:

a) Appearance:

Physical state: liquid, water solution, crystallite size (Scherrer method) ~ 10 nm

Colour: white

b) Odour: Odourless

c) Odour threshold: NA

d) pH: 6-8

e) Melting point/freezing point: approximately 0 degrees C

f) Initial boiling point and boiling grange: approximately 100 degrees C

g) Flash point: NA

h) Evaporation rate: NA

i) Flammability (solid, gas): NA

j) Upper/lower flammability or explosive limits: NA

k) Vapour pressure: ND

l) Vapour density: ND

m) Relative density: (at 20 degrees C) approximately 1,2 g/cm3

n) Solubility(ies):

Water: As the product is water solution it is soluble in water

o) Partition coefficient: n-octanol/water: NA

p) Auto ignition temperature: ND

q) Decomposition temperature: ND

r) Viscosity: ND

s) Explosive properties: Product does not present an explosion hazard.

t) Oxidising properties: it is inert

9.2 Other Information:

Rutile is not photocatalytically active

10 Stability and reactivity

10.1 Reactivity:

10.2 *Chemical stability:* it is stable

10.3 *Possibility of hazardous reactions:* Not known

10.4 *Conditions to avoid:* Heating above the boiling point

10.5 *Incompatible materials:* Not known

10.6 *Hazardous decomposition products:* Not known

11 Toxicological information

11.1 *Information on toxicological effects*

Acute toxicity: According to available data (for powder) the product is not toxic. Since the introduction of TiO_2 as a commercial product (both in powder and suspension) in 1923, there have been no identified health concerns associated with its exposure among consumers or the general population. Pigmentary TiO_2 which meets appropriate purity standards is approved as a colorant for use in foods (E171 - e.g. candies, cookies, sweets, coffee whitener, toothpaste, etc …) and pharmaceuticals (several Pharmacopoeias).

Method: Short-term toxicity to fish and to aquatic invertebrates

Species: *Oncorhynchus mykiss, Pimephales promelas; Daphnia magna*

Routes of exposure: OECD202, OECD203, OECD211

Effective Doses:

Exposure time: 24 to 72 hours

Results: low concern/negative

Skin corrosion/irritation: Does not irritate skin
TiO2 in pigmentary and ultrafine forms is used in cosmetics applications. Studies show TiO2 particles (pigmentary or ultrafine) do not penetrate either intact or damaged skin (8, 9). Based on existing safety information, it can be concluded that the use of titanium dioxide nanomaterial (ultrafine) as an ingredient in cosmetic sunscreen products at a concentration up to 25 % poses no risks to human health (12, 13).

Serious eye damage/irritation: The product can cause eyes irritation

Respiratory or skin sensitisation: No data

Germ cell mutagenicity: According to available data (for powder) the product is not genotoxic (micronucleus test)

Carcinogenicity: According to available data (for powder) the product is not carcinogenic (tests on rat CD,

rat Fischer). Four large epidemiology studies on exposure of worker to ultrafine and pigmentary TiO2 in North America and Europe (1,2,3,4,6,10) found no association with an increased risk of cancer or with any other adverse lung effects (7).

Reproductive toxicity: No data

Summary of evaluation of the CMR properties: No data

STOT-single exposure: No data

STOT-repeated exposure: No data

Aspiration hazard: No danger
for powders: Protection measures including engineering controls and personal protective equipment are applied for exposure control and worker risk mitigation in accordance with existing regulations (7).

Additional toxicological information: To the best of our knowledge the acute and chronic toxicity of this substance is not fully known.

12 Ecological information:

12.1 Toxicity

The product is not toxic, but do not allow material to be released to the environment without proper governmental permits as all possible effects are not known.

Acute (short term) toxicity of rutie 100% (380nm) to fish:
Method/Test: Oncorhynchus mykiss

Guideline: OECD 203

Dose or concentration: 0, 0.1, 1, 10 and 100 mg/L

Results: low concern, LC50 > 100 mg/L

Acute (short term) toxicity of rutie 100% (380nm) to aquatic invertebrates:
Method/Test: Daphnia magna

Guideline: OECD 202

Dose or concentration: 0, 0.1, 1, 10 and 100 mg/L

Results: negative, LC50 > 100 mg/L

Acute (long term) toxicity of rutie 73-83% (L 50 × W 10 nm) to aquatic invertebrates:
Method/Test: Daphnia magna

Guideline: OECD 211

Dose or concentration: 0.01, 0.03, 0.1, 0.3, 1, 3, 10, 30 and 100 mg/L

Results: posetive, LOEC 10 mg/L, NOEC 3mg/L, EC50 26.6 mg/L, EC10 5.02 mg/L

Micronucleous test of rutile (200 nm):

Test: Micronucleus

System: Human BEAS-2B bronchial epithelial cells in vitro

Dose or concentration: 10 μg/mL (1.77 μg/cm^2)

Results: negative

Crustacea:

Acute toxicity of titanium dioxide to aquatic invertebrates:
Particle type: Degussa P25, Hombikate UV100

Particle size: Degussa P25: 25 nm, Hombikate UV100: 100 nm

Method/Test: Daphnia magna

Suspension preparation: ultrasonic dispersion

Observation: TiO_2 Degussa P25 particles were found to entail a large effect than the larger particle type (Hombikate UV100). Pre-illumination of suspension with simulated sunlight was found to increase immobilization of the test organism

Algae/aquatic plants:
Other organisms:

12.2 Persistence and degradability
Abiotic degradation:
Physical- and photo-chemical elimination:
Biodegradation: not biodegradable

12.3 Bioaccumulation potential
Partition coefficient n-octanol/water:
Bioconcentration factor (BCF):

12.4 Mobility in soil
Known or predicted distribution to environmental compartments:
Surface tension:
Adsoprtion/desorption:

12.5 Results of PBT and vPvB assessment

12.6 Other adverse effects

12.7 Additional information

13 Disposal considerations

13.1 Waste treatment methods

13.1.1 Product/packaging disposal: Disposal in agreement with national and regional laws.

13.1.2 Waste treatment-relevant information:

13.1.3 Sewage disposal-relevant information: see point 6

13.1.4 Other disposal recommendations:

14 Transport information

Not a hazardous material for transportation .

- **Land transport ADR/RID (cross-border)**
- **ADR/RID class:** None

- **Maritime transport IMDG:**
- **IMDG Class:** None

- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** None

14.1 UN number:
14.2 UN proper shipping name:
14.3 Transport hazard class: None
14.4 Packing group:
14.5 Environmental hazards:
14.6 Special precautions for user:
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not dangerous according to the above specifications

15 Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:
EU Regulations

Use as a colorant

o Automotive: Council directive 2000/53/EC (end-of life vehicles)

o Cosmetics: Council Directive 76/768/EEC

o Electronic equipment: Council directives 2002/95/EC and 2002/96/EC

o Food: E171 in the European directive 2008/128/EC, replacing 95/45/EC

o Food contact applications: EU Regulation (EU) 10/2011, Council Directive 2004/19/EEC

o Packaging: Council Directive 94/62/EC

o Paints: Volatile Organic Compounds (VOC) according to the definition of the EU directive 2004/42/EC "decopaint directive"

o Pharmaceuticals: European Pharmacopoeia (EP)

o Toys: DIN EN 71-3 (Security of toys)

Use without coloring effect

o Cosmetics: Council Directive 76/768/EEC

Authorisations and/or restrictions on use:

Authorisations:

Restriction on use: For use only by technically qualified individuals.

Other EU regulations:

National regulations:

15.1 Chemical Safety Assessment:

16 <u>Other information:</u>
(i) Indication of changes:
(ii) Abbreviations and acronyms:
(iii) Key literature references and sources of data:
(iv) Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1271/2008 [CLP]
(v) Relevant R-phrases and/or H-statements (number and full text): no

(vi) Training advice: In accordance with the Law on Safety and Health at Work.
(vii) Exposure scenarios (…)
(viii) Further information:

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