

Guttapercha Points

Coltène/Whaledent GmbH & Co. KG

Version No: 2.2

Safety data sheet according to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

Issue Date: 02/11/2022

Print Date: 18/11/2024

L.REACH.GB.EN

SECTION 1 Identification of the substance / mixture and of the company / undertaking

1.1. Product Identifier

Product name	Guttapercha Points
Chemical Name	Not Applicable
Synonyms	Not Available
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide)
Chemical formula	Not Applicable
Other means of identification	Not Available

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Medical device, for dental use only Use according to manufacturer's directions.
Uses advised against	No specific uses advised against are identified.

1.3. Details of the manufacturer or supplier of the safety data sheet

Registered company name	Coltène/Whaledent GmbH & Co. KG
Address	Raiffeisenstrasse 30 89129 Langenau Germany
Telephone	+49 (7345) 805 0
Fax	+49 (7345) 805 201
Website	www.coltene.com
Email	msds@coltene.com

1.4. Emergency telephone number

Association / Organisation	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone number(s)	+44 20 3901 3542
Other emergency telephone number(s)	+44 808 164 9592


Once connected and if the message is not in your preferred language then please dial 01

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 ^[1]	H400 - Hazardous to the Aquatic Environment Acute Hazard Category 1, H410 - Hazardous to the Aquatic Environment Long-Term Hazard Category 1
Legend:	1. Classified by Chemwatch; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567

2.2. Label elements

Hazard pictogram(s)	
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Signal word **Warning**

Hazard statement(s)

H410 Very toxic to aquatic life with long lasting effects.

Supplementary statement(s)

EUH212 Warning! Hazardous respirable dust may be formed when used. Do not breathe in dust.

Precautionary statement(s) Prevention

P273 Avoid release to the environment.

Precautionary statement(s) Response

P391 Collect spillage.

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

P501 Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

Material contains C.I. Pigment White 6.

2.3. Other hazards

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 Composition / information on ingredients

3.1. Substances

See 'Composition on ingredients' in Section 3.2

3.2. Mixtures

1. CAS No 2. EC No 3. Index No 4. REACH No	% [weight]	Name	Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567	SCL / M-Factor	Nanoform Particle Characteristics
1. 1314-13-2 2. 215-222-5 3. 030-013-00-7 4. Not Available	50-70	<u>zinc oxide</u>	Hazardous to the Aquatic Environment Acute Hazard Category 1, Hazardous to the Aquatic Environment Long-Term Hazard Category 1; H400, H410 [2]	SCL: Not Available Acute M factor: 10 Chronic M factor: Not Available	Not Available
1. 13463-67-7 2. 236-675-5 3. 022-006-00-2 4. Not Available	1-5	<u>C.I. Pigment White 6</u>	Carcinogenicity Category 2; H351 [2]	SCL: Not Available Acute M factor: Not Available Chronic M factor: 10	Not Available

Legend:

1. Classified by Chemwatch; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties

SECTION 4 First aid measures

4.1. Description of first aid measures

Eye Contact	If this product comes in contact with eyes: <ul style="list-style-type: none"> ▶ Wash out immediately with water. ▶ If irritation continues, seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs:

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	<ul style="list-style-type: none"> ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

5.1. Extinguishing media

- ▶ Water spray or fog.
- ▶ Foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

5.2. Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.
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5.3. Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use fire fighting procedures suitable for surrounding area. ▶ DO NOT approach containers suspected to be hot. ▶ Cool fire exposed containers with water spray from a protected location. ▶ If safe to do so, remove containers from path of fire. ▶ Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Non combustible. ▶ Not considered a significant fire risk, however containers may burn. <p>Decomposition may produce toxic fumes of:</p> <p>, metal oxides</p>

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

Minor Spills	<p>Environmental hazard - contain spillage.</p> <ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Avoid contact with skin and eyes. ▶ Wear impervious gloves and safety glasses. ▶ Use dry clean up procedures and avoid generating dust. ▶ Vacuum up. ▶ Do NOT use air hoses for cleaning ▶ Place spilled material in clean, dry, sealable, labelled container.
Major Spills	<p>Environmental hazard - contain spillage.</p> <ul style="list-style-type: none"> ▶ Clear area of personnel and move upwind. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Control personal contact with the substance, by using protective equipment and dust respirator. ▶ Prevent spillage from entering drains, sewers or water courses. ▶ Avoid generating dust. ▶ Sweep, shovel up. Recover product wherever possible. ▶ Put residues in labelled plastic bags or other containers for disposal. ▶ If contamination of drains or waterways occurs, advise emergency services.

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6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

7.1. Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Limit all unnecessary personal contact. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Avoid contact with incompatible materials. ▶ When handling, DO NOT eat, drink or smoke. ▶ Avoid physical damage to containers. ▶ Always wash hands with soap and water after handling. ▶ Work clothes should be laundered separately. ▶ Use good occupational work practice.
Fire and explosion protection	See section 5
Other information	<ul style="list-style-type: none"> ▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store away from incompatible materials and foodstuff containers.

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Packing as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<ul style="list-style-type: none"> ▶ Store in original containers. ▶ Store in a cool, dry area protected from environmental extremes. ▶ Store away from incompatible materials and foodstuff containers.
Hazard categories in accordance with Regulation (EC) No 2012/18/EU (Seveso III)	E1: Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1
Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of	E1 Lower- / Upper-tier requirements: 100 / 200

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

Ingredient	DNELs	PNECs
	Exposure Pattern Worker	Compartment
zinc oxide	Dermal 83 mg/kg bw/day (Systemic, Chronic) Inhalation 5 mg/m ³ (Systemic, Chronic) <i>Dermal 83 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 0.0025 mg/m³ (Systemic, Chronic) *</i> <i>Oral 0.83 mg/kg bw/day (Systemic, Chronic) *</i>	0.00019 mg/L (Water (Fresh)) 0.00114 mg/L (Water (Marine)) 18 mg/kg sediment dw (Sediment (Fresh Water)) 6.4 mg/kg sediment dw (Sediment (Marine)) 0.9 mg/kg soil dw (Soil) 0.02 mg/L (STP) 0.16 mg/kg food (Oral)
C.I. Pigment White 6	Inhalation 0.17 mg/m ³ (Local, Chronic) <i>Inhalation 0.028 mg/m³ (Local, Chronic) *</i>	Not Available

* Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
UK Workplace Exposure Limits (WELs).	C.I. Pigment White 6	Titanium dioxide: total inhalable	10 mg/m ³	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs).	C.I. Pigment White 6	Titanium dioxide: respirable	4 mg/m ³	Not Available	Not Available	Not Available

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Ingredient	Original IDLH	Revised IDLH
zinc oxide	500 mg/m ³	Not Available
C.I. Pigment White 6	5,000 mg/m ³	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
zinc oxide	E	≤ 0.01 mg/m ³
Notes:	<i>Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.</i>	

MATERIAL DATA

NOTE: This substance has been classified by the ACGIH as A4 **NOT** classifiable as causing Cancer in humans for zinc oxide:

Zinc oxide intoxication (intoxication zincale) is characterised by general depression, shivering, headache, thirst, colic and diarrhoea.

Exposure to the fume may produce metal fume fever characterised by chills, muscular pain, nausea and vomiting. Short-term studies with guinea pigs show pulmonary function changes and morphologic evidence of small airway inflammation. A no-observed-adverse-effect level (NOAEL) in guinea pigs was 2.7 mg/m³ zinc oxide. Based on present data, the current TLV-TWA may be inadequate to protect exposed workers although known physiological differences in the guinea pig make it more susceptible to functional impairment of the airways than humans.

Animals exposed by inhalation to 10 mg/m³ titanium dioxide show no significant fibrosis, possibly reversible tissue reaction. The architecture of lung air spaces remains intact.

· The label on a package containing 1% or more of titanium oxide with aerodynamic diameter equal or below 10 microns shall bear the following statement:


EUH211 "Warning! Hazardous respirable droplets may be formed when sprayed. Do NOT breathe spray or mist"

· The label on the packaging of solid mixtures containing 1% or more of titanium dioxide shall bear the following statement: EUH212 "Warning! Hazardous respirable dust may be formed when used. Do not breathe dust".

In addition, the label on the packaging of liquid and solid mixtures not intended for the general public and not classified as hazardous which are labelled EUH211 or EU212 shall bear statement EUH210: "Safety data sheet available on request."

The concentration of dust, for application of respirable dust limits, is to be determined from the fraction that penetrates a separator whose size collection efficiency is described by a cumulative log-normal function with a median aerodynamic diameter of 4.0 µm (+-) 0.3 µm and with a geometric standard deviation of 1.5 µm (+-) 0.1 µm, i.e..generally less than 5 µm.

8.2. Exposure controls

8.2.1. Appropriate engineering controls	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.
8.2.2. Individual protection measures, such as personal protective equipment	
Eye and face protection	<ul style="list-style-type: none"> ▶ Safety glasses with side shields ▶ Chemical goggles. ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]
Skin protection	See Hand protection below
Hands/feet protection	<p>Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.</p> <ul style="list-style-type: none"> ▶ polychloroprene. ▶ nitrile rubber. ▶ butyl rubber. ▶ fluorocautchouc. ▶ polyvinyl chloride. <p>Gloves should be examined for wear and/ or degradation constantly.</p>
Body protection	See Other protection below
Other protection	<p>No special equipment needed when handling small quantities.</p> <p>OTHERWISE:</p> <ul style="list-style-type: none"> ▶ Overalls. ▶ Barrier cream. ▶ Eyewash unit.

8.2.3. Environmental exposure controls

See section 12

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SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Not Available		
Physical state	Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Available
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Immiscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Heat of Combustion (kJ/g)	Not Available	Ignition Distance (cm)	Not Available
Flame Height (cm)	Not Available	Flame Duration (s)	Not Available
Enclosed Space Ignition Time Equivalent (s/m ³)	Not Available	Enclosed Space Ignition Deflagration Density (g/m ³)	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

10.1.Reactivity	See section 7.2
10.2. Chemical stability	<ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

SECTION 11 Toxicological information

11.1. Information on toxicological effects

Eye					
Chronic					
Guttapercha Points	<table border="1"> <tr> <th>TOXICITY</th> <th>IRRITATION</th> </tr> <tr> <td>Not Available</td> <td>Not Available</td> </tr> </table>	TOXICITY	IRRITATION	Not Available	Not Available
TOXICITY	IRRITATION				
Not Available	Not Available				

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	TOXICITY	IRRITATION
	zinc oxide	dermal (rat) LD50: >2000 mg/kg ^[1]
Inhalation (Rat) LC50: >1.79 mg/l4h ^[1]		Eye: no adverse effect observed (not irritating) ^[1]
Oral (Rat) LD50: >5000 mg/kg ^[1]		Skin (Human): 300ug/3D (intermittent) - Mild
		Skin (Rodent - rabbit): 500mg/24H - Mild
		Skin: no adverse effect observed (not irritating) ^[1]
	TOXICITY	IRRITATION
	C.I. Pigment White 6	dermal (hamster) LD50: >=10000 mg/kg ^[2]
Inhalation (Rat) LC50: >2.28 mg/l4h ^[1]		Skin (Human): 300ug/3D (intermittent) - Mild
Oral (Rat) LD50: >=2000 mg/kg ^[1]		Skin: no adverse effect observed (not irritating) ^[1]
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

Acute Toxicity	✘	Carcinogenicity	✘
Skin Irritation/Corrosion	✘	Reproductivity	✘
Serious Eye Damage/Irritation	✘	STOT - Single Exposure	✘
Respiratory or Skin sensitisation	✘	STOT - Repeated Exposure	✘
Mutagenicity	✘	Aspiration Hazard	✘

Legend: ✘ – Data either not available or does not fill the criteria for classification
 ✔ – Data available to make classification

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

Guttapercha Points	Endpoint	Test Duration (hr)	Species	Value	Source
		Not Available	Not Available	Not Available	Not Available
zinc oxide	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	96h	Algae or other aquatic plants	0.042mg/L	2
	BCF	1344h	Fish	19-110	7
	EC50	72h	Algae or other aquatic plants	0.022mg/L	2
	EC10(ECx)	168h	Algae or other aquatic plants	0.003mg/L	2
	EC50	48h	Crustacea	0.105mg/L	2
	ErC50	72h	Algae or other aquatic plants	0.62mg/l	2
LC50	96h	Fish	0.102mg/L	2	
C.I. Pigment White 6	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	96h	Algae or other aquatic plants	179.05mg/l	2
	BCF	1008h	Fish	<1.1-9.6	7
	EC50	72h	Algae or other aquatic plants	3.75-7.58mg/l	4
	NOEC(ECx)	672h	Fish	>=0.004mg/L	2
EC50	48h	Crustacea	1.9mg/l	2	

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	LC50	96h	Fish	1.85-3.06mg/l	4
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
C.I. Pigment White 6	HIGH	HIGH

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
zinc oxide	LOW (BCF = 217)
C.I. Pigment White 6	LOW (BCF = 10)

12.4. Mobility in soil

Ingredient	Mobility
C.I. Pigment White 6	LOW (Log KOC = 23.74)

12.5. Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT	✘	✘	✘
vPvB	✘	✘	✘
PBT Criteria fulfilled?	No		
vPvB	No		

12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.



SECTION 13 Disposal considerations

13.1. Waste treatment methods

Product / Packaging disposal	Dispose of waste according to applicable legislation. Special country-specific regulations may apply. Can be disposed together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge. (Only dispose of completely emptied packages.)
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 Transport information

Labels Required

	
Marine Pollutant	
HAZCHEM	2Z

Guttapercha Points

Land transport (ADR-RID)

14.1. UN number or ID number	3077	
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide)	
14.3. Transport hazard class(es)	Class	9
	Subsidiary Hazard	Not Applicable
14.4. Packing group	III	
14.5. Environmental hazard	Environmentally hazardous	
14.6. Special precautions for user	Hazard identification (Kemler)	90
	Classification code	M7
	Hazard Label	9
	Special provisions	274 335 375 601
	Limited quantity	5 kg
	Tunnel Restriction Code	Not Applicable

Air transport (ICAO-IATA / DGR)

14.1. UN number	3077	
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (contains zinc oxide)	
14.3. Transport hazard class(es)	ICAO/IATA Class	9
	ICAO / IATA Subsidiary Hazard	Not Applicable
	ERG Code	9L
14.4. Packing group	III	
14.5. Environmental hazard	Environmentally hazardous	
14.6. Special precautions for user	Special provisions	A97 A158 A179 A197 A215
	Cargo Only Packing Instructions	956
	Cargo Only Maximum Qty / Pack	400 kg
	Passenger and Cargo Packing Instructions	956
	Passenger and Cargo Maximum Qty / Pack	400 kg
	Passenger and Cargo Limited Quantity Packing Instructions	Y956
	Passenger and Cargo Limited Maximum Qty / Pack	30 kg G

Sea transport (IMDG-Code / GGVSee)

14.1. UN number	3077	
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide)	
14.3. Transport hazard class(es)	IMDG Class	9
	IMDG Subsidiary Hazard	Not Applicable
14.4. Packing group	III	
14.5. Environmental hazard	Marine Pollutant	
14.6. Special precautions for user	EMS Number	F-A, S-F
	Special provisions	274 335 966 967 969
	Limited Quantities	5 kg

Inland waterways transport (ADN)

14.1. UN number	3077	
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide)	
	9	Not Applicable

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14.3. Transport hazard class(es)		
14.4. Packing group	III	
14.5. Environmental hazard	Environmentally hazardous	
14.6. Special precautions for user	Classification code	M7
	Special provisions	274; 335; 375; 601
	Limited quantity	5 kg
	Equipment required	PP, A***
	Fire cones number	0

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
zinc oxide	Not Available
C.I. Pigment White 6	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
zinc oxide	Not Available
C.I. Pigment White 6	Not Available

SECTION 15 Regulatory information

15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture

zinc oxide is found on the following regulatory lists

Great Britain GB Biocidal Active Substances

Great Britain GB mandatory classification and labelling list (GB MCL)

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

C.I. Pigment White 6 is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List

Great Britain GB mandatory classification and labelling list (GB MCL)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

UK Workplace Exposure Limits (WELs).

Additional Regulatory Information

Not Applicable

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

Information according to 2012/18/EU (Seveso III):

Seveso Category	E1
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15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

National Inventory Status

National Inventory	Status
Australia - AIIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (C.I. Pigment White 6)
China - IECSC	Yes

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National Inventory	Status
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	All chemical substances in this product have been designated as TSCA Inventory 'Active'
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - FBEPH	Yes
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	02/11/2022
Initial Date	31/01/2022

Full text Risk and Hazard codes

H351	Suspected of causing cancer.
H400	Very toxic to aquatic life.

SDS Version Summary

Version	Date of Update	Sections Updated
1.2	02/11/2022	Toxicological information - Chronic Health, Hazards identification - Classification, Exposure controls / personal protection - Exposure Standard, Composition / information on ingredients - Ingredients

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

Definitions and abbreviations

- PC - TWA: Permissible Concentration-Time Weighted Average
- PC - STEL: Permissible Concentration-Short Term Exposure Limit
- IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit,
- IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard
- OSF: Odour Safety Factor
- NOAEL: No Observed Adverse Effect Level
- LOAEL: Lowest Observed Adverse Effect Level
- TLV: Threshold Limit Value
- LOD: Limit Of Detection
- OTV: Odour Threshold Value
- BCF: BioConcentration Factors
- BEI: Biological Exposure Index
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration

Guttapercha Points

- ▶ MARPOL: International Convention for the Prevention of Pollution from Ships
- ▶ IMSBC: International Maritime Solid Bulk Cargoes Code
- ▶ IGC: International Gas Carrier Code
- ▶ IBC: International Bulk Chemical Code

- ▶ AIIC: Australian Inventory of Industrial Chemicals
- ▶ DSL: Domestic Substances List
- ▶ NDSL: Non-Domestic Substances List
- ▶ IECSC: Inventory of Existing Chemical Substance in China
- ▶ EINECS: European INventory of Existing Commercial chemical Substances
- ▶ ELINCS: European List of Notified Chemical Substances
- ▶ NLP: No-Longer Polymers
- ▶ ENCS: Existing and New Chemical Substances Inventory
- ▶ KECL: Korea Existing Chemicals Inventory
- ▶ NZIoC: New Zealand Inventory of Chemicals
- ▶ PICCS: Philippine Inventory of Chemicals and Chemical Substances
- ▶ TSCA: Toxic Substances Control Act
- ▶ TCSI: Taiwan Chemical Substance Inventory
- ▶ INSQ: Inventario Nacional de Sustancias Químicas
- ▶ NCI: National Chemical Inventory
- ▶ FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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