

Coltosol F

Coltène/Whaledent AG

Version No: 1.1

Safety Data Sheet according to OSHA HazCom Standard (2012) requirements

Issue Date: **31/03/2022**

Print Date: **15/02/2024**

S.GHS.USA.EN

SECTION 1 Identification

Product Identifier

Product name	Coltosol F
Synonyms	Not Available
Proper shipping name	Environmentally hazardous substance, solid, n.o.s. (contains zinc oxide)
Other means of identification	Not Available

Recommended use of the chemical and restrictions on use

Relevant identified uses	Medical device, for dental use only Use according to manufacturer's directions.
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Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

Registered company name	Coltène/Whaledent AG
Address	Feldwiesenstrasse 20 Altstätten CH-9450 Switzerland
Telephone	+41 (71) 75 75 300
Fax	+41 (71) 75 75 301
Website	www.coltene.com
Email	msds@coltene.com

Emergency phone number

Association / Organisation	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone numbers	+1 855-237-5573
Other emergency telephone numbers	+61 3 9573 3188

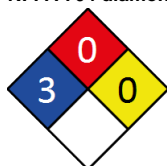
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SECTION 2 Hazard(s) identification

Classification of the substance or mixture

NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification	Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 1, Hazardous to the Aquatic Environment Acute Hazard Category 1, Hazardous to the Aquatic Environment Long-Term Hazard Category 1
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Coltosol F

Label elements

Hazard pictogram(s)	  
Signal word	Danger

Hazard statement(s)

H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H410	Very toxic to aquatic life with long lasting effects.

Hazard(s) not otherwise classified

Not Applicable

Precautionary statement(s) Prevention

P280	Wear protective gloves, protective clothing, eye protection and face protection.
P261	Avoid breathing mist/vapours/spray.
P273	Avoid release to the environment.
P272	Contaminated work clothing must not be allowed out of the workplace.

Precautionary statement(s) Response

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor/physician/first aider.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
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.
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SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
1314-13-2	25-35	<u>zinc oxide</u>
7446-19-7	10-15	<u>zinc sulfate monohydrate</u>
8006-90-4	<1	<u>peppermint oil</u>

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 First-aid measures

Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▸ Immediately hold eyelids apart and flush the eye continuously with running water. ▸ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally
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Continued...

Coltosol F

	lifting the upper and lower lids. ▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▶ Transport to hospital or doctor without delay. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin contact occurs: ▶ Immediately remove all contaminated clothing, including footwear. ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	▶ If swallowed do NOT induce vomiting. ▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. ▶ Observe the patient carefully. ▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. ▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. ▶ Seek medical advice.

Most important symptoms and effects, both acute and delayed

See Section 11

Indication of any immediate medical attention and special treatment needed

- ▶ Absorption of zinc compounds occurs in the small intestine.
- ▶ The metal is heavily protein bound.
- ▶ Elimination results primarily from faecal excretion.
- ▶ The usual measures for decontamination (Ipecac Syrup, lavage, charcoal or cathartics) may be administered, although patients usually have sufficient vomiting not to require them.
- ▶ CaNa₂EDTA has been used successfully to normalise zinc levels and is the agent of choice.

[Ellenhorn and Barceloux: Medical Toxicology]

SECTION 5 Fire-fighting measures**Extinguishing media**

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

Special hazards arising from the substrate or mixture

Fire Incompatibility	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Special protective equipment and precautions for fire-fighters

Fire Fighting	▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use water delivered as a fine spray to control fire and cool adjacent 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	Combustible. Will burn if ignited. Combustion products include: carbon monoxide (CO) carbon dioxide (CO ₂) sulfur oxides (SO _x) sulfur dioxide (SO ₂) metal oxides other pyrolysis products typical of burning organic material.

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Coltosol F**SECTION 6 Accidental release measures****Personal precautions, protective equipment and emergency procedures**

See section 8

Environmental precautions

See section 12

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 goggles. ▸ Trowel up/scrape up. ▸ Place spilled material in clean, dry, sealed container. ▸ Flush spill area with water.
Major Spills	<ul style="list-style-type: none"> ▸ Clear area of personnel and move upwind. ▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear breathing apparatus plus protective gloves. ▸ Prevent, by any means available, spillage from entering drains or water course. ▸ Stop leak if safe to do so. ▸ Contain spill with sand, earth or vermiculite. ▸ Collect recoverable product into labelled containers for recycling. ▸ Neutralise/decontaminate residue (see Section 13 for specific agent). ▸ Collect solid residues and seal in labelled drums for disposal. ▸ Wash area and prevent runoff into drains. ▸ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. ▸ If contamination of drains or waterways occurs, advise emergency services. <p>Environmental hazard - contain spillage.</p>

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

SECTION 7 Handling and storage**Precautions for safe handling**

Safe handling	<ul style="list-style-type: none"> ▸ Avoid all personal contact, including inhalation. ▸ Wear protective clothing when risk of exposure occurs. ▸ Use in a well-ventilated area. ▸ Prevent concentration in hollows and sumps. ▸ Avoid contact with incompatible materials. ▸ Keep containers securely sealed when not in use. ▸ Avoid physical damage to containers. ▸ Always wash hands with soap and water after handling. ▸ Work clothes should be laundered separately. Launder contaminated clothing before re-use. ▸ Use good occupational work practice. ▸ Observe manufacturer's storage and handling recommendations contained within this SDS. ▸ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
Other information	<ul style="list-style-type: none"> ▸ Store in original containers. ▸ Keep containers securely sealed. ▸ Store in a cool, dry, well-ventilated area. ▸ Store away from incompatible materials and foodstuff containers. ▸ Protect containers against physical damage and check regularly for leaks. ▸ Observe manufacturer's storage and handling recommendations contained within this SDS.

Conditions for safe storage, including any incompatibilities

Suitable container	<p>Recommended storage temperature: 15 - 23 °C</p> <ul style="list-style-type: none"> ▸ Packaging as recommended by manufacturer. ▸ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<ul style="list-style-type: none"> ▸ Avoid strong acids, bases. ▸ Avoid reaction with oxidising agents

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SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
US OSHA Permissible Exposure Limits (PELs) Table Z-1	zinc oxide	Zinc oxide- Total dust	15 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	zinc oxide	Zinc oxide fume	5 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	zinc oxide	Zinc oxide- Respirable fraction	5 mg/m3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	zinc oxide	Inert or Nuisance Dust: Total Dust	15 mg/m3 / 50 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	zinc oxide	Inert or Nuisance Dust: Respirable fraction	5 mg/m3 / 15 mppcf	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)	zinc oxide	Zinc oxide - Dust	5 mg/m3	Not Available	15 mg/m3	Not Available
US NIOSH Recommended Exposure Limits (RELs)	zinc oxide	Zinc oxide - Fume	5 mg/m3	10 mg/m3	Not Available	Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
zinc oxide	10 mg/m3	15 mg/m3	2,500 mg/m3
zinc sulfate monohydrate	15 mg/m3	97 mg/m3	580 mg/m3

Ingredient	Original IDLH	Revised IDLH
zinc oxide	500 mg/m3	Not Available
zinc sulfate monohydrate	Not Available	Not Available
peppermint oil	Not Available	Not Available

Occupational Exposure Banding


Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
zinc sulfate monohydrate	E	≤ 0.01 mg/m³
peppermint oil	E	≤ 0.1 ppm

Notes:	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.
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Exposure controls

Appropriate engineering controls	<p>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.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard 'physically' away from the worker and ventilation that strategically 'adds' and 'removes' air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying 'escape' velocities which, in turn, determine the 'capture velocities' of fresh circulating air required to effectively remove the contaminant.</p>
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Coltosol F

	Type of Contaminant:	Air Speed:										
	solvent, vapours, degreasing etc., evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min)										
	aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)										
	direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min)										
	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)										
Within each range the appropriate value depends on:												
<table><tr><td>Lower end of the range</td><td>Upper end of the range</td></tr><tr><td>1: Room air currents minimal or favourable to capture</td><td>1: Disturbing room air currents</td></tr><tr><td>2: Contaminants of low toxicity or of nuisance value only</td><td>2: Contaminants of high toxicity</td></tr><tr><td>3: Intermittent, low production.</td><td>3: High production, heavy use</td></tr><tr><td>4: Large hood or large air mass in motion</td><td>4: Small hood - local control only</td></tr></table>			Lower end of the range	Upper end of the range	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents	2: Contaminants of low toxicity or of nuisance value only	2: Contaminants of high toxicity	3: Intermittent, low production.	3: High production, heavy use	4: Large hood or large air mass in motion	4: Small hood - local control only
Lower end of the range	Upper end of the range											
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents											
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3: Intermittent, low production.	3: High production, heavy use											
4: Large hood or large air mass in motion	4: Small hood - local control only											
<p>Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.</p>												
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. [AS/NZS 1337.1, EN166 or national equivalent]▶ 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].											
Skin protection	See Hand protection below											
Hands/feet protection	<ul style="list-style-type: none">▶ Wear chemical protective gloves, e.g. PVC.▶ Wear safety footwear or safety gumboots, e.g. Rubber <p>NOTE:</p> <ul style="list-style-type: none">▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.											
Body protection	See Other protection below											
Other protection	<ul style="list-style-type: none">▶ Overalls.▶ P.V.C apron.▶ Barrier cream.▶ Skin cleansing cream.▶ Eye wash unit.											

Respiratory protection

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	White
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Coltosol F

Physical state	Free-flowing Paste	Relative density (Water = 1)	2.4
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 Available
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

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Coltosol F	TOXICITY		IRRITATION	
	Not Available		Not Available	
zinc oxide	TOXICITY		IRRITATION	
	dermal (rat) LD50: >2000 mg/kg ^[1]		Eye (rabbit) : 500 mg/24 h - mild	
	Inhalation(Rat) LC50: >1.79 mg/l4h ^[1]		Eye: no adverse effect observed (not irritating) ^[1]	
	Oral (Rat) LD50: >5000 mg/kg ^[1]		Skin (rabbit) : 500 mg/24 h- mild	
			Skin: no adverse effect observed (not irritating) ^[1]	
zinc sulfate monohydrate	TOXICITY		IRRITATION	
	dermal (rat) LD50: >2000 mg/kg ^[1]		Not Available	

Continued...

Coltosol F

	Oral (Mouse) LD50; 200 mg/kg ^[2]	
peppermint oil	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >5000 mg/kg ^[2]	Not Available
	Oral (Rat) LD50: 2426 mg/kg ^[2]	
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

SECTION 12 Ecological information

Toxicity

Coltosol F	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	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
	ErC50	72h	Algae or other aquatic plants	0.62mg/l	2
	EC50	48h	Crustacea	0.105mg/L	2
	EC50	72h	Algae or other aquatic plants	0.022mg/L	2
	EC10(ECx)	168h	Algae or other aquatic plants	0.003mg/L	2
	LC50	96h	Fish	0.102mg/L	2
zinc sulfate monohydrate	Endpoint	Test Duration (hr)	Species	Value	Source
	BCF	1344h	Fish	59-112	7
	EC50	48h	Crustacea	0.06mg/l	4
	EC50	96h	Algae or other aquatic plants	0.0101mg/l	4
	EC50	72h	Algae or other aquatic plants	0.01-0.122mg/l	4
	EC20(ECx)	72h	Algae or other aquatic plants	0.001-0.075mg/l	4
	LC50	96h	Fish	0.000017-0.000034mg/l	4
peppermint oil	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	48h	Crustacea	2.7mg/l	2
	EC50	96h	Algae or other aquatic plants	2.61mg/l	2
	EC50(ECx)	96h	Algae or other aquatic plants	2.61mg/l	2
	LC50	96h	Fish	3.4mg/l	2
	EC50	48h	Crustacea	2.43mg/l	2
	EC50	96h	Algae or other aquatic plants	2.63mg/l	2
	EC50(ECx)	48h	Crustacea	2.43mg/l	2
	LC50	96h	Fish	3.01mg/l	2

Continued...

Coltosol F

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
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DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
zinc sulfate monohydrate	HIGH	HIGH

Bioaccumulative potential

Ingredient	Bioaccumulation
zinc oxide	LOW (BCF = 217)
zinc sulfate monohydrate	LOW (BCF = 112)

Mobility in soil

Ingredient	Mobility
zinc sulfate monohydrate	LOW (KOC = 6.124)



SECTION 13 Disposal considerations

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.)
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SECTION 14 Transport information

Labels Required

	
Marine Pollutant	

Shipping container, transport vehicle placarding, and labeling may vary from the below information. This depends on the quantity shipped, the applicability of excepted quantity requirements, limited quantity requirements, and/or special provisions according to US DOT, IATA and IMDG regulations. In case of reshipment, it is the responsibility of the shipper to determine the appropriate labels and markings in accordance with applicable transport regulations.

Land transport (DOT)

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 Label	9
	Special provisions	8, 146, 335, 384, 441, A112, B54, B120, IB8, IP3, N20, N91, T1, TP33

Coltosol F

For Individual Packages of Environmentally Hazardous Substances meeting the descriptions of UN 3077 or UN 3082 that contain LESS THAN the reportable quantity (5 kg or 5 L) - Not Regulated

For Individual Packages of Environmentally Hazardous Substances meeting the descriptions of UN 3077 or UN 3082 that contain MORE THAN the reportable quantity (5 kg or 5 L) - Regulated and classified as below:

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	

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
zinc sulfate monohydrate	Not Available
peppermint oil	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
zinc oxide	Not Available
zinc sulfate monohydrate	Not Available
peppermint oil	Not Available

SECTION 15 Regulatory information

Coltosol F

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

zinc oxide is found on the following regulatory lists

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

US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2.5

US - Massachusetts - Right To Know Listed Chemicals

US CWA (Clean Water Act) - Priority Pollutants

US CWA (Clean Water Act) - Toxic Pollutants

US DOE Temporary Emergency Exposure Limits (TEELs)

US EPA Integrated Risk Information System (IRIS)

US EPCRA Section 313 Chemical List

US NIOSH Recommended Exposure Limits (RELs)

US OSHA Permissible Exposure Limits (PELs) Table Z-1

US OSHA Permissible Exposure Limits (PELs) Table Z-3

US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

zinc sulfate monohydrate is found on the following regulatory lists

US - Massachusetts - Right To Know Listed Chemicals

US CWA (Clean Water Act) - List of Hazardous Substances

US CWA (Clean Water Act) - Priority Pollutants

US CWA (Clean Water Act) - Toxic Pollutants

US DOE Temporary Emergency Exposure Limits (TEELs)

US EPA Integrated Risk Information System (IRIS)

US EPCRA Section 313 Chemical List

US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

peppermint oil is found on the following regulatory lists

US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

Additional Regulatory Information

Not Applicable

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 hazard categories

Flammable (Gases, Aerosols, Liquids, or Solids)	No
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	No
Acute toxicity (any route of exposure)	No
Reproductive toxicity	No
Skin Corrosion or Irritation	No
Respiratory or Skin Sensitization	Yes
Serious eye damage or eye irritation	Yes
Specific target organ toxicity (single or repeated exposure)	No
Aspiration Hazard	No
Germ cell mutagenicity	No

Continued...

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Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)

Name	Reportable Quantity in Pounds (lb)	Reportable Quantity in kg
zinc sulfate monohydrate	1000	454

US. EPCRA Section 313 Toxic Release Inventory (TRI) (40 CFR 372)

This product contains the following EPCRA section 313 chemicals subject to the reporting requirements of section 313 of the Emergency Planning and Community Right-To-Know-Act of 1986 (40 CFR 372):

CAS No	%[weight]	Name
1314-13-2	25-35	zinc oxide
7446-19-7	10-15	zinc sulfate monohydrate

This information must be included in all SDSs that are copied and distributed for this material.

Additional Federal Regulatory Information

Not Applicable

State Regulations

US. California Proposition 65

None Reported

Additional State Regulatory Information

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (zinc sulfate monohydrate; peppermint oil)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (peppermint oil)
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - FBEPH	Yes
Legend:	<i>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.</i>

SECTION 16 Other information

Revision Date	31/03/2022
Initial Date	18/01/2022

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.

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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.

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