

CORTISOMOL SP

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** CORTISOMOL SP
- Other means of identification:**
Non-applicable
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Powder for sealing cement for root canals - product for professional dental use.
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
ACTEON MANUFACTURING
ZI DU PHARE - 17 AVENUE GUSTAVE EIFFEL
33700 MERIGNAC - GIRONDE - FRANCE
- 1.4 Emergency telephone number:** +33(0)5 56 34 06 07 Business hours

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
CLP Regulation (EC) No 1272/2008:
Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.
Aquatic Acute 1: Hazardous to the aquatic environment, acute hazard, Category 1, H400
Aquatic Chronic 1: Hazardous to the aquatic environment, long-term hazard, Category 1, H410
Skin Sens. 1B: Sensitisation, skin, Category 1B, H317
- 2.2 Label elements:**
CLP Regulation (EC) No 1272/2008:
Warning
- 

- Hazard statements:**
Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects.
Skin Sens. 1B: H317 - May cause an allergic skin reaction.
- Precautionary statements:**
P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P272: Contaminated work clothing should not be allowed out of the workplace.
P273: Avoid release to the environment.
P280: Wear protective gloves/protective clothing/respiratory protection/eye protection/protective footwear.
P302+P352: IF ON SKIN: Wash with plenty of water.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P391: Collect spillage.
P501: Dispose of contents/container in accordance with regulations on hazardous waste or packaging and packaging waste respectively.
- Substances that contribute to the classification**
5,5'-diisopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihypiodite (CAS: 552-22-7)
- 2.3 Other hazards:**
Product fails to meet PBT/vPvB criteria
Endocrine-disrupting properties: The product fails to meet the criteria.
May form explosible dust-air mixture if dispersed

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**
Non-applicable
- 3.2 Mixture:**

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

Chemical description: Mixture of organic and inorganic substances

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification		Concentration
CAS: 1314-13-2 EC: 215-222-5 Index: 030-013-00-7 REACH: 01-2119463881-32-XXXX	zinc oxide⁽¹⁾	ATP CLP00	50 - <75 %
	Regulation 1272/2008	Aquatic Acute 1: H400; Aquatic Chronic 1: H410 - Warning 	
CAS: 552-22-7 EC: 209-007-5 Index: Non-applicable REACH: Non-applicable	5,5'-diisopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihypiodite⁽¹⁾	Self-classified	10 - <25 %
	Regulation 1272/2008	Skin Sens. 1B: H317 - Warning 	
CAS: 7727-43-7 EC: 231-784-4 Index: Non-applicable REACH: 01-2119491274-35-XXXX	Barium Sulfate⁽²⁾	Not classified	10 - <25 %
	Regulation 1272/2008		
CAS: 52-21-1 EC: 200-134-1 Index: Non-applicable REACH: Non-applicable	Prednisolone 21-acetate⁽¹⁾	Self-classified	1 - <2,5 %
	Regulation 1272/2008	Repr. 2: H361d; STOT RE 2: H373 - Warning 	

⁽¹⁾ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

⁽²⁾ Substance with a Union workplace exposure limit

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product is not classified as hazardous through inhalation. However, in case of intoxication symptoms it is recommended to remove the person affected from the area of exposure, provide clean air and keep at rest. Request medical attention if symptoms persist.

By skin contact:

May cause an allergic skin reaction. In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes on the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

By eye contact:

This product does not contain substances classified as hazardous for eye contact. Rinse eyes thoroughly for at least 15 minutes with lukewarm water, ensuring that the person affected does not rub or close their eyes.

By ingestion/aspiration:

In case of consumption, seek immediate medical assistance showing the SDS for the product.

4.2 Most important symptoms and effects, both acute and delayed:

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

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SECTION 5: FIREFIGHTING MEASURES (continued)

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

For emergency responders:

See section 8.

6.2 Environmental precautions:

Avoid at all cost any type of spillage into an aqueous medium. Contain the product absorbed appropriately in hermetically sealed containers. Notify the relevant authority in case of exposure to the general public or the environment.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and destroy using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

Due to its inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal See sections 8 and 13.

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Maximum Temp.: 25 °C

B.- General conditions for storage

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SECTION 7: HANDLING AND STORAGE (continued)

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

Other information:

Keep the product in its original pack and tightly close.

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

Directive (EU) 2000/39, Directive 2004/37/EC, Directive (EU) 2006/15, Directive (EU) 2009/161, Directive (EU) 2017/164, Directive (EU) 2019/1831:

Identification	Occupational exposure limits		
Barium Sulfate CAS: 7727-43-7 EC: 231-784-4	IOELV (8h)		0,5 mg/m ³
	IOELV (STEL)		

Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
zinc oxide CAS: 1314-13-2 EC: 215-222-5	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	83 mg/kg	Non-applicable
	Inhalation	Non-applicable	Non-applicable	5 mg/m ³	0,5 mg/m ³
Barium Sulfate CAS: 7727-43-7 EC: 231-784-4	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Inhalation	Non-applicable	Non-applicable	10 mg/m ³	10 mg/m ³

DNEL (General population):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
zinc oxide CAS: 1314-13-2 EC: 215-222-5	Oral	Non-applicable	Non-applicable	0,83 mg/kg	Non-applicable
	Dermal	Non-applicable	Non-applicable	83 mg/kg	Non-applicable
	Inhalation	Non-applicable	Non-applicable	2,5 mg/m ³	Non-applicable
Barium Sulfate CAS: 7727-43-7 EC: 231-784-4	Oral	Non-applicable	Non-applicable	13000 mg/kg	Non-applicable
	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Inhalation	Non-applicable	Non-applicable	10 mg/m ³	Non-applicable

PNEC:

Identification					
zinc oxide CAS: 1314-13-2 EC: 215-222-5	STP	0,1 mg/L	Fresh water		0,0206 mg/L
	Soil	35,6 mg/kg	Marine water		0,0061 mg/L
	Intermittent	Non-applicable	Sediment (Fresh water)		117,8 mg/kg
	Oral	Non-applicable	Sediment (Marine water)		56,5 mg/kg
Barium Sulfate CAS: 7727-43-7 EC: 231-784-4	STP	62,2 mg/L	Fresh water		0,115 mg/L
	Soil	207,7 mg/kg	Marine water		Non-applicable
	Intermittent	Non-applicable	Sediment (Fresh water)		600,4 mg/kg
	Oral	Non-applicable	Sediment (Marine water)		Non-applicable

8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory respiratory tract protection	Filter mask for gases, vapours and particles		EN 149:2001+A1:2009 EN 405:2002+A1:2010 EN ISO 136:1998	Replace when an increase in resistance to breathing is observed and/or a smell or taste of the contaminant is detected.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420:2004+A1:2010 and EN ISO 374-1:2016+A1:2018

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application.

D.- Eye and face protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against splash/projections.		EN 166:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
	Anti-slip work shoes		EN ISO 20347:2012	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345:2012 y EN 13832-1:2007

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m ³ (0 g/L)
Average carbon number:	Non-applicable

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Average molecular weight:	Non-applicable
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Solid
Appearance:	Powdery
Colour:	 Beige
Odour:	Not available
Odour threshold:	Non-applicable *

Volatility:

Boiling point at atmospheric pressure:	Non-applicable *
Vapour pressure at 20 °C:	Non-applicable *
Vapour pressure at 50 °C:	Non-applicable *
Evaporation rate at 20 °C:	Non-applicable *

Product description:

Density at 20 °C:	2194,1 kg/m ³
Relative density at 20 °C:	2,194
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *

Flammability:

Flash Point:	Non-applicable
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

Explosive (Solid):

Lower explosive limit:	Non-applicable *
Upper explosive limit:	Non-applicable *

Particle characteristics:

Median equivalent diameter:	Non-applicable *
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9.2 Other information:

Information with regard to physical hazard classes:

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Corrosive to metals:	Non-applicable *
Heat of combustion:	Non-applicable *
Aerosols-total percentage (by mass) of flammable components:	Non-applicable *

Other safety characteristics:

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for consumption. For more information see section 3
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):
 - Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
IARC: Non-applicable
 - Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
 - Reproductive toxicity: Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.
- E- Sensitizing effects:
 - Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.
 - Skin: Prolonged contact with the skin can result in episodes of allergic contact dermatitis.
- F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- G- Specific target organ toxicity (STOT)-repeated exposure:
 - Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met. However, it does contain substances which are classified as dangerous due to repetitive exposure. For more information see section 3.
 - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
zinc oxide CAS: 1314-13-2 EC: 215-222-5	LD50 oral	7950 mg/kg	Mouse
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation	>5 mg/L	
Prednisolone 21-acetate CAS: 52-21-1 EC: 200-134-1	LD50 oral	>2000 mg/kg	
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation	Non-applicable	
5,5'-diisopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihypiodite CAS: 552-22-7 EC: 209-007-5	LD50 oral	>2000 mg/kg	
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation	Non-applicable	
Barium Sulfate CAS: 7727-43-7 EC: 231-784-4	LD50 oral	>5000 mg/kg	Rat
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation	>5 mg/L	

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product fails to meet the criteria.

Other information

Non-applicable

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SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

Acute toxicity:

Identification	Concentration	Species	Genus
zinc oxide	LC50 0,82 mg/L (96 h)	Oncorhynchus kisutch	Fish
CAS: 1314-13-2	EC50 3,4 mg/L (48 h)	Daphnia magna	Crustacean
EC: 215-222-5	EC50 Non-applicable		
Barium Sulfate	LC50 76000 mg/L (96 h)	Salmo gairdneri	Fish
CAS: 7727-43-7	EC50 Non-applicable		
EC: 231-784-4	EC50 Non-applicable		

Chronic toxicity:

Identification	Concentration	Species	Genus
zinc oxide	NOEC 0,44 mg/L	Oncorhynchus mykiss	Fish
CAS: 1314-13-2 EC: 215-222-5	NOEC 0,031 mg/L	Daphnia magna	Crustacean
Barium Sulfate	NOEC 100 mg/L	Danio rerio	Fish
CAS: 7727-43-7 EC: 231-784-4	NOEC Non-applicable		

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Product fails to meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product fails to meet the criteria.

12.7 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
	It is not possible to assign a specific code, as it depends on the intended use by the user	Dangerous

Type of waste (Regulation (EU) No 1357/2014):

HP14 Ecotoxic, HP13 Sensitising

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

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SECTION 14: TRANSPORT INFORMATION (continued)

Transport of dangerous goods by land:

With regard to ADR 2021 and RID 2021:



- | | |
|--|---|
| 14.1 UN number or ID number: | UN3077 |
| 14.2 UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide) |
| 14.3 Transport hazard class(es): | 9 |
| Labels: | 9 |
| 14.4 Packing group: | III |
| 14.5 Environmental hazards: | Yes |
| 14.6 Special precautions for user | |
| Special regulations: | 274, 335, 375, 601 |
| Tunnel restriction code: | - |
| Physico-Chemical properties: | see section 9 |
| Limited quantities: | 5 kg |
| 14.7 Maritime transport in bulk according to IMO instruments: | Non-applicable |

Transport of dangerous goods by sea:

With regard to IMDG 40-20:



- | | |
|--|---|
| 14.1 UN number or ID number: | UN3077 |
| 14.2 UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide) |
| 14.3 Transport hazard class(es): | 9 |
| Labels: | 9 |
| 14.4 Packing group: | III |
| 14.5 Marine pollutant: | Yes |
| 14.6 Special precautions for user | |
| Special regulations: | 335, 966, 274, 967, 969 |
| EmS Codes: | F-A, S-F |
| Physico-Chemical properties: | see section 9 |
| Limited quantities: | 5 kg |
| Segregation group: | Non-applicable |
| 14.7 Maritime transport in bulk according to IMO instruments: | Non-applicable |

Transport of dangerous goods by air:

With regard to IATA/ICAO 2022:



- | | |
|--|---|
| 14.1 UN number or ID number: | UN3077 |
| 14.2 UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide) |
| 14.3 Transport hazard class(es): | 9 |
| Labels: | 9 |
| 14.4 Packing group: | III |
| 14.5 Environmental hazards: | Yes |
| 14.6 Special precautions for user | |
| Physico-Chemical properties: | see section 9 |
| 14.7 Maritime transport in bulk according to IMO instruments: | Non-applicable |

SECTION 15: REGULATORY INFORMATION

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

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SECTION 15: REGULATORY INFORMATION (continued)

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable
Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable
Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable
Article 95, REGULATION (EU) No 528/2012: Non-applicable
REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Seveso III:

Section	Description	Lower-tier requirements	Upper-tier requirements
E1	ENVIRONMENTAL HAZARDS	100	200

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

Non-applicable

Texts of the legislative phrases mentioned in section 2:

H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
H317: May cause an allergic skin reaction.

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Aquatic Acute 1: H400 - Very toxic to aquatic life.
Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects.
Repr. 2: H361d - Suspected of damaging the unborn child.
Skin Sens. 1B: H317 - May cause an allergic skin reaction.
STOT RE 2: H373 - May cause damage to organs through prolonged or repeated exposure.

Classification procedure:

Aquatic Acute 1: Calculation method
Aquatic Chronic 1: Calculation method
Skin Sens. 1B: Calculation method

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>
<http://eur-lex.europa.eu>

Abbreviations and acronyms:

- CONTINUED ON NEXT PAGE -

CORTISOMOL SP**SECTION 16: OTHER INFORMATION (continued)**

ADR: European agreement concerning the international carriage of dangerous goods by road
IMDG: International maritime dangerous goods code
IATA: International Air Transport Association
ICAO: International Civil Aviation Organisation
COD: Chemical Oxygen Demand
BOD5: 5day biochemical oxygen demand
BCF: Bioconcentration factor
LD50: Lethal Dose 50
LC50: Lethal Concentration 50
EC50: Effective concentration 50
LogPOW: Octanolwater partition coefficient
Koc: Partition coefficient of organic carbon
UFI: unique formula identifier
IARC: International Agency for Research on Cancer

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -