

# Safety Data Sheet

## ELITE ORTHO WHITE

Revision nr. 4  
Dated 19/06/2023

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

#### 1.1. Product identifier

Mixture identification:  
Product Name: ELITE ORTHO WHITE  
Code: C410090, C410091, C410092, C410230, C410320

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

For professional use only. Stone for orthodontic models.

#### 1.3. Details of the supplier of the safety data sheet

Name  
Zhermack S.p.a  
Via Bovazecchino 100  
45021 Badia Polesine (RO)  
Italy  
tel. +39 0425-597611  
fax +39 0425-597689

Competent person responsible for the safety data sheet:  
msds@zhermack.com

#### 1.4. Emergency telephone number

+39 0425 597611 (office hours)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

#### 2.2. Label elements

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

None

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

#### 2.3. Other hazards

No PBT, vPvB or endocrine disruptor substances present in concentration  $\geq 0.1\%$

Other Hazards:

No other hazards

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

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Not Applicable

**3.2. Mixtures**

Hazardous components within the meaning of the CLP regulation and related classification:  
None.

**SECTION 4: First aid measures****4.1. Description of first aid measures**

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

**4.2. Most important symptoms and effects, both acute and delayed**

None

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

Treatment:

None

**SECTION 5: Firefighting measures****5.1. Extinguishing media**

Suitable extinguishing media:

Water.

Carbon dioxide (CO<sub>2</sub>).

Extinguishing media which must not be used for safety reasons:

None in particular.

**5.2. Special hazards arising from the substance or mixture**

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

**5.3. Advice for firefighters**

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

For non emergency personnel:

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

For emergency responders:

Wear personal protection equipment.

**6.2. Environmental precautions**

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

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#### 6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

#### 6.4. Reference to other sections

See also section 8 and 13

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

Do not eat or drink while working.

#### 7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.

Incompatible materials:

See section 10.5.

Instructions as regards storage premises:

Adequately ventilated premises.

#### 7.3. Specific end use(s)

See section 1.2.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

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DNEL Exposure Limit Values

Not available

PNEC Exposure Limit Values

Not available

#### 8.2. Exposure controls

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.

Eye protection:

Wear airtight protective goggles (EN 166).

Protection for skin:

Wear professional overalls and safety footwear (EN 14605).

Protection for hands:

Protect hands with work gloves (EN 374).

The following should be considered when choosing work glove material (EN 374): compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

Respiratory protection:

Use respiratory protection where ventilation is insufficient or exposure is prolonged.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered (e.g. TLV-TWA).

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

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Properties	Value	Method:	Notes
Physical state:	Dust	--	--
Colour:	White	--	--
Odour:	Odourless	--	--
Melting point/freezing point:	Not available	--	--
Boiling point or initial boiling point and boiling range:	Not available	--	--
Flammability:	Not available	--	--
Lower and upper explosion limit:	Not available	--	--
Flash point:	Not available	--	--
Auto-ignition temperature:	Not available	--	--
Decomposition temperature:	Not available	--	--
pH:	Not available	--	--
Kinematic viscosity:	Not available	--	--
Solubility in water:	Partially soluble	--	--
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or relative density:	Not available	--	--
Relative vapour density:	Not available	--	--
Particle characteristics:			
Particle size:	Not available	--	--

#### 9.2. Other information

No other relevant information

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Stable under normal conditions

#### 10.2. Chemical stability

Stable under normal conditions

#### 10.3. Possibility of hazardous reactions

None

#### 10.4. Conditions to avoid

Stable under normal conditions.

#### 10.5. Incompatible materials

None in particular.

#### 10.6. Hazardous decomposition products

None.

### SECTION 11: Toxicological information

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

Toxicological information of the product:  
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- a) acute toxicity  
Not classified
- b) skin corrosion/irritation  
Not classified
- c) serious eye damage/irritation  
Not classified
- d) respiratory or skin sensitisation  
Not classified
- e) germ cell mutagenicity  
Not classified
- f) carcinogenicity  
Not classified
- g) reproductive toxicity  
Not classified
- h) STOT-single exposure  
Not classified
- i) STOT-repeated exposure  
Not classified
- j) aspiration hazard  
Not classified

Toxicological information of the main substances found in the product:  
Not available

**11.2. Information on other hazards**

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration  $\geq 0.1\%$

**SECTION 12: Ecological information****12.1. Toxicity**

Adopt good working practices, so that the product is not released into the environment.

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Not classified for environmental hazards

Based on available data, the classification criteria are not met

**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**

vPvB Substances: None - PBT Substances: None

**12.6. Endocrine disrupting properties**

No endocrine disruptor substances present in concentration  $\geq 0.1\%$

**12.7. Other adverse effects**

None

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Recover if possible. In so doing, comply with the local and national regulations currently in force.

**SECTION 14: Transport information****14.1. UN number or ID number**

Not classified as dangerous in the meaning of transport regulations.

**14.2. UN proper shipping name**

Not available

**14.3. Transport hazard class(es)**

Not available

**14.4. Packing group**

Not available

**14.5. Environmental hazards**

ADR-Environmental Pollutant: No

IMDG-Marine pollutant: No

**14.6. Special precautions for user**

Not available

**14.7. Maritime transport in bulk according to IMO instruments**

Not Applicable

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Regulation (EU) n. 2020/878

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)

Regulation (EU) n. 605/2014 (ATP 6 CLP)

Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Regulation (EU) n. 2016/918 (ATP 8 CLP)

Regulation (EU) n. 2016/1179 (ATP 9 CLP)

Regulation (EU) n. 2017/776 (ATP 10 CLP)

Regulation (EU) n. 2018/669 (ATP 11 CLP)

Regulation (EU) n. 2018/1480 (ATP 13 CLP)

Regulation (EU) n. 2019/521 (ATP 12 CLP)

Regulation (EU) n. 2020/217 (ATP 14 CLP)

Regulation (EU) n. 2020/1182 (ATP 15 CLP)

Regulation (EU) n. 2021/643 (ATP 16 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

No restriction.

Restrictions related to the substances contained:

No restriction.

Provisions related to directive EU 2012/18 (Seveso III):

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Seveso III category according to Annex 1, part 1  
None

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)  
WGK1 - Slightly hazardous for water

Lagerklasse according to TRGS 510:  
LGK 10: Combustible liquids

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:  
None.

California Proposition 65  
Substance(s) listed under California Proposition 65:  
None.

**15.2. Chemical safety assessment**

No Chemical Safety Assessment has been carried out for the mixture.  
Substances for which a Chemical Safety Assessment has been carried out:  
None

**SECTION 16: Other information**

This safety data sheet has been completely updated in compliance to Regulation 2020/878.

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECHA – European Chemical Agency  
GESTIS - Information system on hazardous substances of the German Social Accident Insurance  
IARC – International Agency for Research on Cancer  
IPCS INCHEM – International Programme on Chemical Safety  
ISS – Istituto Superiore di Sanità  
PubChem - open chemistry database at the National Institutes of Health (NIH)

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.  
ATE: Acute Toxicity Estimate  
ATEmix: Acute toxicity Estimate (Mixtures)  
CAS: Chemical Abstracts Service (division of the American Chemical Society).  
CLP: Classification, Labeling, Packaging.  
DNEL: Derived No Effect Level.  
EINECS: European Inventory of Existing Commercial Chemical Substances.  
GefStoffVO: Ordinance on Hazardous Substances, Germany.  
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.

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IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.