

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 14.08.2024

Version number 6 (replaces version 5)

Revision: 14.08.2024

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

- **1.1 Product identifier**
- **Trade name: COE-SOFT Powder**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Auxillary for dental technology
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
GC EUROPE N.V.  
Interleuvenlaan 33  
B-3001 Leuven  
Tel. +32/(0)16/74.10.00  
Fax +32/(0)16/40.26.84  
msds@gc.dental
- **Further information obtainable from:** Regulatory affairs
- **1.4 Emergency telephone number:** International: +01-813-248-0585 (ChemTel Inc.)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Exemptions**  
The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

- **3.2 Mixtures**
- **Description:**  
Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.
- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**  
No special measures required.  
If symptoms persist consult doctor.
- **After inhalation:** Take affected persons into fresh air and keep quiet.
- **After skin contact:** Immediately rinse with water.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.  
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**  
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Remove persons from danger area.
- **6.2 Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
Do not allow to penetrate the ground/soil.
- **6.3 Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Dispose of the material collected according to regulations.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Prevent formation of dust.

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- Any unavoidable deposit of dust must be regularly removed.
- **Information about fire - and explosion protection:** Dust can combine with air to form an explosive mixture.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in unopened original receptacles.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.  
Do not inhale dust / smoke / mist.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **Hand protection** Protective gloves
- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection** Safety glasses

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Colour:** Pink
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Not determined.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.

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· <b>Auto-ignition temperature:</b>	Undetermined.
· <b>Decomposition temperature:</b>	Not determined.
· <b>pH</b>	Not applicable.
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not applicable.
· <b>Dynamic:</b>	Not applicable.
· <b>Solubility</b>	
· <b>water:</b>	Insoluble.
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density and/or relative density</b>	
· <b>Density at 20 °C:</b>	0.61 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Particle characteristics</b>	
See section 3.	

· **9.2 Other information**

· <b>Appearance:</b>	
· <b>Form:</b>	Powder
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not applicable.

· **Information with regard to physical hazard classes**

· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

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- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

**SECTION 11: Toxicological information**

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:** No further relevant information available.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information**

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.  
Contact waste processors for recycling information.

- **European waste catalogue**

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing hazardous substances

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- **14.1 UN number or ID number**  
· **ADR, ADN, IMDG, IATA** not regulated
- **14.2 UN proper shipping name**  
· **ADR, ADN, IMDG, IATA** not regulated
- **14.3 Transport hazard class(es)**  
· **ADR, ADN, IMDG, IATA**  
· **Class** not regulated
- **14.4 Packing group**  
· **ADR, IMDG, IATA** not regulated
- **14.5 Environmental hazards:**  
· **Marine pollutant:** No
- **14.6 Special precautions for user** Not applicable.
- **14.7 Maritime transport in bulk according to IMO instruments** Not applicable.
- **UN "Model Regulation":** not regulated

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

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· **REGULATION (EU) 2019/1148**· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information**· **Classification according to Regulation (EC) No 1272/2008** Calculation method· **Department issuing SDS:** Regulatory affairs· **Contact:** msds@gc.dental· **Date of previous version:** 30.06.2023· **Version number of previous version:** 5· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· **Sources**· ECHA (<http://echa.europa.eu/>)· EnviChem ([www.echemportal.org](http://www.echemportal.org))· **\* Data compared to the previous version altered.**

This version replaces all previous versions.

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