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1 Identification of the substance or mixture and of the supplier

- · Product identifier
- · Trade name: COE-SOFT Powder
- 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
- · Details of the supplier of the safety data sheet

Henry Schein Dental

243-249 Bush Road, Rosedale Auckland 0632, NEW ZEALAND

Free Phone: 0800 808 855

- · Further information obtainable from: Regulatory affairs
- · Emergency telephone number: 0800 764 766 (National Poisons Centre)

2 Hazards identification

· Classification of the substance or mixture

The product is not classified, according to the Globally Harmonised System (GHS).

- · Label elements
- · GHS label elements 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
- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable. · **vPvB:** Not applicable.

3 Composition/Information on ingredients

- · Chemical characterisation: 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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4 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.

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire fighting measures

· Suitable extinguishing agents:

CO2, 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
- · 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.

- · Protective equipment: Wear self-contained respiratory protective device.
- · Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Remove persons from danger area.
- · Environmental precautions:

Do not allow product to reach sewage system or any water course.

Do not allow to penetrate the ground/soil.

· Methods and material for containment and cleaning up:

Pick up mechanically.

Dispose of the material collected according to regulations.

· 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.

7 Handling and storage

- · Handling:
- · Precautions for safe handling

Prevent formation of dust.

Any unavoidable deposit of dust must be regularly removed.

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- · Information about fire and explosion protection: Dust can combine with air to form an explosive mixture.
- · 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.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see section 7.
- · 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.
- · 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.
- · Protection of hands: 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 protection: Safety glasses

9 Physical and chemical properties

· General Information

· Appearance:

· Form: Powder · Colour: Pink

Odour: Characteristic
Odour threshold: Not determined.
pH-value: Not applicable.

Change in condition

Melting point/freezing point:
 Initial boiling point and boiling range: Undetermined.
 Flash point:
 Flammability (solid, gas):
 Auto-ignition temperature:
 Decomposition temperature:
 Undetermined.
 Not determined.
 Not determined.

• Ignition temperature: Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

· **Lower:** Not determined.

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Upper: Not determined.
 Vapour pressure: Not applicable.
 Density at 20 °C: 0.61 g/cm³
 Relative density Not determined.
 Vapour density Not applicable.
 Evaporation rate Not applicable.

· Solubility in / Miscibility with

• water: Insoluble. • Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not applicable.Kinematic: Not applicable.

• Other information No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on toxicological effects
- · 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 (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.

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- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · 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.

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

not regulated	
not regulated	
not regulated	
not regulated	
No	
Not applicable.	
of Marpol	
Not applicable.	
	not regulated not regulated not regulated No Not applicable. of Marpol

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · New Zealand Inventory of Chemicals

All ingredients are listed.

· HSNO Approval numbers

None of the ingredients is listed.

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- · **GHS label elements** Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- · 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

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)
- * Data compared to the previous version altered.

This version replaces all previous versions.

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