

Printing date 01/10/2019

Version US-EN-Rev 3

Reviewed on 01/10/2019

1 Identification

- · Product identifier
- · Trade name: COE-SOFT (Powder)
- · Relevant identified uses of the substance or mixture and uses advised against

Dental material

The product is intended for professional use.

To avoid risks for humans and environment obtain instructions.

- · Application of the substance / the mixture Manufacture of dental prothesis
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

GC America Inc. 3737 W. 127th Street Alsip, IL 60803 USA

sds@gcamerica.com

- · Information department: Regulatory Affairs
- · Emergency telephone number:

During normal opening times (Monday–Friday 8:00 AM–5:00 PM Central Time): +1 (708) 597-0900 Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard(s) identification

· Classification of the substance or mixture

Combustible Dust May form combustible dust concentrations in air.

· Additional information:

The information provided is in regards to the toxicity and hazard rating(s) of the individual component(s) in the formulation. The associated risk(s) depends on the route(s) of exposure. The hazard rating system is based entirely on the existence of the risk(s) and does not take into account the likelihood of reduced risk(s) through proper usage and handling.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- · Hazard pictograms Void
- Signal word Warning
- · Hazard statements

May form combustible dust concentrations in air.

- · Hazard not otherwise classified (HNOC): None known.
- Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

- US

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3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · **Description:** Mixture of the substances listed below with nonhazardous additions.
- · Dangerous components:

CAS: 557-08-4 zinc undecylenate

2.5 - < 5%

· Additional information:

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

4 First-aid measures

- Description of first aid measures
- **General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

No special measures required.

If symptoms persist consult doctor.

After inhalation:

Supply fresh air; consult doctor in case of complaints.

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Rinse with warm water.

Seek medical treatment.

If symptoms persist consult doctor.

· 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

- · Extinguishing media
- · Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire fighting measures that suit the environment.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Carbon monoxide and carbon dioxide

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Flammable gases/vapors

Poisonous gases/vapors

- Advice for firefighters
- Protective equipment:

Mouth respiratory protective device.

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.

Avoid contact with the eyes and skin.

· 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 collected material 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.

Protective Action Criteria for Chemicals

Protective Action Criterion (PAC); Protective Action Criteria (PACs); Lower Explosive Limit (LEL)

- * indicates the PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ PAC < 50% LEL).
- ** indicates the PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC < 100% LEL).
- *** indicates the PAC value is at 100% or more of the LEL (PAC ≥ LEL).

excerpt from Introduction to PAC Table 2 - PAC Rev. 29 - May 2016

· PAC-1:	
CAS: 13463-67-7 titanium dioxide	30 mg/m³
· PAC-2:	
CAS: 13463-67-7 titanium dioxide	330 mg/m³
PAC-3:	
CAS: 13463-67-7 titanium dioxide	2,000 mg/m³

7 Handling and storage

· Handling:

· Precautions for safe handling

Observe instructions for use.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of dust.

Any deposit of dust which cannot be avoided must be regularly removed.

Avoid contact with the eyes and skin.

Information about protection against explosions and fires:

Dust can combine with air to form an explosive mixture.

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- · 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:

Observe instructions for use / storage.

Keep receptacle tightly sealed.

· Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components 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 that were valid during the creation were used as basis.
- Exposure controls
- Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Do not inhale dust / smoke / mist.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Breathing equipment:



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:

Manufacturing sites:

Wear safety glasses with side shields (or goggles).

Distribution, Workplace, and Household Settings:

No special protective equipment required

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· General Information

· Appearance:

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9 Physical and chemical properties

· Information on basic physical and chemical properties

Form: Color: Odor: Odor threshold:	Powder Pink Characteristic Not determined.
· pH-value:	Not applicable.
 Change in condition Melting point/Melting range: Boiling point/Boiling range: 	121 °C (249.8 °F) Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.
· Ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not self-igniting.

Risk of dust explosion.

Not determined.

Not determined.

Not applicable.

Insoluble.

Explosion limits: Lower:

· Vapor pressure:

Upper:

· Danger of explosion:

Density: Not determined.
 Bulk density: 610 kg/m³
 Relative density Not determined.
 Vapor density Not applicable.
 Evaporation rate Not applicable.

· Solubility in / Miscibility with

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

Dynamic:Kinematic:
Not applicable.
Not applicable.

· Solvent content:

 VOC content:
 0.00 %

 Solids content:
 100.0 %

• Other information No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.

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- · Chemical stability Stable at ambient temperature.
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions Risk of dust explosion.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products:

Carbon monoxide

Flammable gases/vapors

Poisonous gases/vapors

Carbon dioxide

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification: No further relevant information available.
- · Primary irritant effect:
- · on the skin: No irritant effect.
- on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations.

Carcinogenic categories

IARC (International Agency for Research on Cancer)

titanium dioxide

2B

NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Carcinogenic categories' legend:

IARC Group 1: The agent is carcinogenic to humans.

IARC Group 2A: The agent is probably carcinogenic to humans.

IARC Group 2B: The agent is possibly carcinogenic to humans.

IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.

IARC Group 4: The agent is probably not carcinogenic to humans.

NTP K: Known to be human carcinogen.

NTP R: Reasonably anticipated to be human carcinogen.

- · Repeated dose toxicity. No further relevant information available.
- · CMR effects (carcinogenicity, 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.

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- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes:

Water hazard class 1 (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.

- · 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:

Dispose of contents / container in accordance with local / regional / national / international regulations.

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

14 Transport information	
· UN-Number · DOT, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA · Class	Void
· Packing group · DOT, ADR, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of Not applicable.
· UN "Model Regulation":	Void

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15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · SARA (Superfund Amendments and Reauthorization Act)
- · Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

TSCA (Toxic Substances Control Act):

All ingredients are listed.

- · Carcinogenic categories
- · EPA (Environmental Protection Agency)

None of the ingredients is listed.

EPA carcinogenic categories' legend:

EPA weight-of-evidence (WOE) (1986 guidelines, but still valid)

- A: human carcinogen
- B1: probable carcinogen, limited human evidence
- B2: probable carcinogen, sufficient evidence in animals
- C: possible human carcinogen
- D: not classifiable
- E: evidence of noncarcinogenicity

TLV (Threshold Limit Value established by ACGIH)

titanium dioxide

A4

· ACGIH carcinogenic categories' legend:

- A1: confirmed human carcinogen
- A2: suspected human carcinogen
- A3: confirmed animal carcinogen with unknown relevance to humans
- A4: not classifiable as a human carcinogen
- A5: not suspected as a human carcinogen

· NIOSH-Ca (National Institute for Occupational Safety and Health)

titanium dioxide

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- Hazard pictograms Void
- · Signal word Warning
- · Hazard statements

May form combustible dust concentrations in air.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

- Department issuing SDS: Regulatory Affairs
- · Contact:

Regulatory Affairs

Telephone No. +1 (708) 597-0900

sds@gcamerica.com

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Abbreviations and acronyms:

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

HCS: Hazard Communication Standard (USA)

MSDS: Material Safety Data Sheet

SDS: Safety Data Sheet

ADN: Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways)

ECHA: European Chemicals Agency

OSHA: Occupational Safety and Health Administration (USA)

PAC: Protective Action Criterion (USA) PACs: Protective Action Criteria (USA)

HNOC: Hazard Not Otherwise Classified (USA)

LEL: Lower Explosive Limit UEL: Upper Explosive Limit

OSHA-Ca: Occupational Safety and Health Administration - Carcinogens or potential carcinogens regulated (USA)

NIOSH-Ca: National Institute for Occupational Safety and Health - Carcinogen List (USA)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

· Sources

- Manufacturers' MSDSs/SDSs
- OSHA (https://www.osha.gov/dts/chemicalsampling/toc/chmcas.html)
- TOXNET (http://toxnet.nlm.nih.gov/)
- ECHA (http://echa.europa.eu/)
- EnviChem (www.echemportal.org)

· Notes:

CAS Registry Number is a Registered Trademark of the American Chemical Society. CHEMTREC® is a registered service mark of the American Chemistry Council, Inc.

* Data compared to the previous version altered. This version replaces all previous versions.

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