

COE-COMFORT - POWDER MATERIAL SAFETY DATA SHEET

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SECTION 1 - SOURCE/IDENTITY/USE INFORMATION

MANUFACTURER

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COMMON NAME: COE-COMFORT POWDER

CHEMICAL NAME: N.A.

PRODUCT USE: Dental tissue conditioner - powder component

The following information is provided with regard to the toxicity and hazards of the pure components present in this portion of the unmixed powder/liquid system.

SECTION 2 - HAZARDOUS INGREDIENTS/IDENTITY INFORMATION

COMPONENT	C.A.S.	EXPOSURE LIMITS	LD50/LC50	%
Zinc undecylenate	112-38-9	N.E.	LD50=2.5g/kg	1-5
			(oral rat)	
			LC50=N.E.	

SECTION 3 - PHYSICAL/CHEMICAL PROPERTIES

BOILING POINT: N.A.	SPECIFIC GRAVITY (H2O = 1):	N.A.
VAPOR PRESSURE: N.A.	MELTING POINT:	N.E.
VAPOR DENSITY: N.A.	EVAPORATION RATE:	N.E.
SOLUBILITY IN WATER: N.E.	ODOR THRESHOLD:	N.A.
COEFFICIENT OF OIL/WATER DISTRIBUTION: N.E.	APPEARANCE AND ODOR:	White odorless powder

SECTION 4 - FIRE AND EXPLOSION DATA

FLASH POINT: N.A.

FLAMMABLE LIMITS: N.E.

EXTINGUISHING MEDIA: Water fog, foam, carbon dioxide, dry chemical **SPECIAL FIRE FIGHTING PROCEDURES:** Self-contained breathing apparatus with full face piece and protective clothing.

UNUSUAL FIRE AND EXPLOSION HAZARDS: Dust explosion hazard

HAZARDOUS COMBUSTION PRODUCTS: Carbon dioxide, carbon monoxide, methyl methacrylate

SECTION 5 - REACTIVITY DATA

STABILITY: POLYMERIZATION: Stable 🖂 Will Not Occur 🖂

Uns	table [
Will	Occur	

CONDITIONS TO AVOID: High heat; strong acids or alkalies INCOMPATIBILITY (MATERIALS TO AVOID): Strong acids or alkalies HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: N.E.

SECTION 6 - HEALTH HAZARD DATA AND FIRST AID INFORMATION

	YES	NO	NE	NA	NTP	IARC	OSHA	OTHER
MUTAGENIC AFFECTS		X						
TERATOGENIC AFFECTS		X						
REPRODUCTIVE TOXIN		X						
CARCINOGENICITY		Х						
SENSITIZER		Х						



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SECTION 6 - HEALT	H HAZARD DATA AN	D FIRST AID INFORMA	TION - continued	
ROUTES OF ENTRY:	Inhalation 🔀	Skin 🔀	Ingestion 🔀	
SIGNS AND SYMPTOM	te and Chronic): Ingest S OF OVEREXPOSURE: LLY AGGRAVATED BY B	N.E.	l vomiting. May cause eye	e irritation.
<i>INGESTION:</i> Giv <i>SKIN:</i> Wash wit	emove victim to fresh a ve one or two glasses o h soap and water.	f water to drink. If gastro	intestinal symptoms develo burning sensation develop	op, seek medical attention. os, seek medical attention.
SECTION 7 - PRECA	UTIONS FOR SAFE H	ANDLING AND USE		
Wash spill area with h	ot water and detergent FHOD : In accordance v	vith local, state, federal re		d shovel into waste container. neat or open flame.
SECTION 8 - CONTR	OL MEASURES			
RESPIRATORY PROTE respirator for dusts, m		sure in accordance with g	good hygiene practice. Us	e MSHA-NIOSH approved
VENTILATION: Loca	al Exhaust: N.E.	Mechanical: N.E.	Special: N.E.	Other: N.E.
EYE PROTECTION: Sa OTHER PROTECTIVE O	Disposable vinyl glov fety glasses LOTHING OR EQUIPME CTICE: Follow safe hyg	NT: Eyewash station		
SECTION 9- PREPAI	RATION INFORMATI	ON		
This data is supplied to a	comply with OSHA Hazar	d Communication Standard	29 CFR 1910,1200 and W.H.	.M.I.S. CPR
DATE: <u>09 January 20</u> REVIEWED: <u>20 Fo</u>				
N.A. = NOT APPLICA N.E. = NOT ESTABLI				
The information herein i	s given in good faith. No	warranty expressed or impl	ied is made.	
FIRE – 0	TOXICITY -	NFPA 1 REA	ACTIVITY – 0	SPECIAL – OXY



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Safety data sheet

according to 1907/2006/EC, Article 31 Printing date 14.08.2015 Version number 2 Revision: 12.08.2015 SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: Coe Comfort 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)16/74.10.00Fax +32/(0)16/40.26.84 msds@gceurope.com · Further information obtainable from: Regulatory affairs · 1.4 Emergency telephone number: National poison center for United Kingdom of Great Britain and Northern Ireland: Belfast: +44 28 90 63 2032 Birmingham: +44 121 507 4123 Edinburgh: +44 131 242 1383 Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180 Penarth: +44 292 071 55 54 **SECTION 2: Hazards identification** · 2.1 Classification of the substance or mixture Classification according to Regulation (EC) No 1272/2008 Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device. Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects. · 2.2 Label elements · Labelling according to Regulation (EC) No 1272/2008 Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device. The product is classified and labelled according to the CLP regulation. · Hazard pictograms Void · Signal word Void · Hazard statements H412 Harmful to aquatic life with long lasting effects. · Precautionary statements P273 Avoid release to the environment.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

• 2.3 Other hazards

- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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1-5%

SECTION 3: Composition/information on ingredients

· 3.2 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:

CAS: 112-38-9 Undec-10-enoic acid

EINECS: 203-965-8 Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319

• Additional information: For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

• 4.1 Description of first aid measures

· General information: If symptoms persist consult doctor.

• After inhalation:

Supply fresh air and to be sure call for a doctor.

- Take affected persons into fresh air and keep quiet.
- After skin contact: If skin irritation continues, consult a 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.
- 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:

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
- 5.2 Special hazards arising from the substance or mixture
- Formation of toxic gases is possible during heating or in case of fire.
- 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.

Avoid formation of dust.

Wear protective clothing.

6.2 Environmental precautions:

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

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to penetrate the ground/soil.

In case of seepage into the ground inform responsible authorities.

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• 6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

Prevent formation of dust.

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.

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

• Additional information about design of technical facilities: No further data; see item 7.

· 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

- · 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

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9.1 Information on basic physical a	und chemical properties
General Information	
Appearance:	
Form:	Powder
Colour:	White
Odour:	<i>Characteristic</i>
Odour threshold:	Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not determined.
Ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
Self-igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not applicable.
Density at 20 °C:	$0.6 g/cm^3$
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
water:	Insoluble.
Partition coefficient (n-octanol/wat	ter): Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solvent content:	
Organic solvents:	0.0 %
9.2 Other information	No further relevant information available.

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.

• 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.

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SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

• Acute toxicity

· LD/LC50 values relevant for classification:

112-38-9 Undec-10-enoic acid

Oral LD50 2500 mg/kg (rat (f+m))

Primary irritant effect:

• 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.
- Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- No further relevant information available.
- 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.
- $\cdot \textit{STOT-repeated exposure Based on available data, the classification criteria are not met.}$
- Aspiration hazard Based on available data, the classification criteria are not met.

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.
- Ecotoxical effects:
- · Remark: Harmful to fish
- Additional ecological information:

• General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground. Harmful to aquatic organisms

· 12.5 Results of PBT and vPvB assessment

- **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

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.

• 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 dangerous substances

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· Uncleaned packaging:

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• Recommendation: Disposal must be made according to official regulations.

14.1 UN-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 Transport in bulk according to Ann. Marpol and the IBC Code	ex II of 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 No further relevant information available.

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

SECTION 16: Other information

· Relevant phrases

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.

Classification according to Regulation (EC) No 1272/2008 Calculation method

· Department issuing MSDS: Regulatory affairs

· Contact: msds@gceurope.com

• Abbreviations and acronyms:

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 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

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2

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Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3 · 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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