

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.07.2022

Version number 1


Revision: 22.07.2022

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

- **1.1 Product identifier**
- **Trade name: GC EXA Advanced (Regular base - normal set, normal set (Tube type))**
- **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** Auxiliary 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
- **Information department:** 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**
STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labeled according to the CLP regulation.
- **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**

GHS08
- **Signal word** Danger
- **Hazard-determining components of labeling:**
Quartz
- **Hazard statements**
H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Precautionary statements**
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P264 Wash thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P314 Get medical advice/attention if you feel unwell.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterization: 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:

14808-60-7	Quartz STOT RE 1, H372	25-<50%
68037-59-2	Methylhydrogen dimethylpolysiloxane Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-<5%

- **Additional information:** For the wording of the listed hazard 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. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. 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, 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

· 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.

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· **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.

Wear protective clothing.

· **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:**

Absorb liquid components with liquid-binding material.

Dispose of the collected material 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**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· **Information about protection against explosions and fires:** No special measures required.

· **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**

· **Additional information about design of technical systems:** No further data; see item 7.

· **Components with limit values that require monitoring at the workplace:**

14808-60-7 Quartz

BOELV	Long-term value: 0.1* mg/m ³ *respirable fraction
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· **Additional information:** The lists that were valid during the creation were used as basis.

· **8.2 Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

· **Breathing equipment:** Suitable respiratory protective device recommended.

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- **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

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Pasty
· Color:	Blue
· Odor:	Odorless
· Odor threshold:	Not determined.

· **pH-value:** Not determined.

· Change in condition

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Ignition temperature:** Undetermined.

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· Explosion limits:

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapor pressure:** Not determined.

· **Density:** Not determined.

2,56 g/cm³
1,18g/ml

· **Relative density** Not determined.

· **Vapor density** Not determined.

· **Evaporation rate** Not determined.

· Solubility in / Miscibility with

· **Water:** Insoluble.

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

· Viscosity:

· **Dynamic:** Not determined.

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Kinematic:	Not determined.
Solvent content: VOC (EC)	0.0 g/l
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.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:** Based on available data, the classification criteria are not met.
- **LD/LC50 values that are relevant for classification:** No further relevant information available.
- **Primary irritant effect:**
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:** Based on available data, the classification criteria are not met.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, 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.
- **Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - repeated exposure**
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **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.

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- **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.
- **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 of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN-Number
· ADR, IMDG, IATA | not regulated |
| · 14.2 UN proper shipping name
· DOT, ADR, 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: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | 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**

- **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

- **Section 313 (Specific toxic chemical listings):**

1345-16-0 Cobalt aluminate blue spinel

- **Chemicals known to cause cancer:**

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· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

14808-60-7 Quartz

A2

· **MAK (German Maximum Workplace Concentration)**

14808-60-7 Quartz

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

14808-60-7 Quartz

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **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.

· **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

· **Relevant phrases**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H372 Causes damage to organs through prolonged or repeated exposure.

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

· **Department issuing SDS:** Regulatory affairs

· **Contact:** msds@gc.dental

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· **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

DOT: US Department of Transportation

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)

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

OSHA: Occupational Safety & Health

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

· **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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