

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

Printing date 25.07.2024



Version number 3 (replaces version 2)

Revision: 25.07.2024

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

- **1.1 Product identifier**
- **Trade name: GC Fuji ORTHO BAND PASTE PAK Paste B**
- **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**
Eye Dam. 1 H318 Causes serious eye damage.
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 labelled 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**

GHS05 GHS08
- **Signal word** Danger
- **Hazard-determining components of labelling:**
Tartaric acid
Quartz
- **Hazard statements**
H318 Causes serious eye damage.
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.

(Contd. on page 2)

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

Printing date 25.07.2024

Version number 3 (replaces version 2)

Revision: 25.07.2024

Trade name: GC_Fuji_ORTHO_BAND_PASTE_PAK_Paste_B

(Contd. of page 1)

- P264 Wash thoroughly after handling.
 P280 Wear eye protection / face protection.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P310 Immediately call a POISON CENTER/doctor.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

- 1.2 % of the mixture consists of component(s) of unknown toxicity.
 Contains 1.2 % of components with unknown hazards to the aquatic environment.

· **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:**

9003-01-4	Polyacrylic acid	Eye Irrit. 2, H319	25-<50%
14808-60-7	Quartz	STOT RE 1, H372 substance with a Community workplace exposure limit	10-<25%
87-69-4	Tartaric acid	Eye Dam. 1, H318	5-<10%

- **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:**

Immediately remove any clothing soiled by the product.
 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:**

Seek medical treatment.
 If skin irritation continues, consult a doctor.

· **After eye contact:**

Protect unharmed eye.
 Rinse opened eye for several minutes under running water.
 Call a doctor immediately.

· **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.

(Contd. on page 3)

Safety data sheet
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Version number 3 (replaces version 2)

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Trade name: GC_Fuji_ORTHO_BAND_PASTE_PAK_Paste_B

(Contd. of page 2)

- **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, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water
- **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.
Avoid contact with the eyes and skin.
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.
- **6.3 Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Avoid contact with the eyes and skin.
- **Information about fire - and explosion protection:** Protect against electrostatic charges.
- **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:** Keep container tightly sealed.

(Contd. on page 4)

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

Printing date 25.07.2024

Version number 3 (replaces version 2)

Revision: 25.07.2024

Trade name: GC_Fuji_ORTHO_BAND_PASTE_PAK_Paste_B

(Contd. of page 3)

· 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:**

14808-60-7 Quartz

BOELV	Long-term value: 0.1* mg/m ³ *respirable fraction
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· **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.

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

· **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**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· **General Information**

· **Physical state**

Fluid

· **Colour:**

White

· **Odour:**

Odourless

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range** Undetermined.

(Contd. on page 5)

EU

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

Printing date 25.07.2024

Version number 3 (replaces version 2)

Revision: 25.07.2024

Trade name: GC_Fuji_ORTHO_BAND_PASTE_PAK_Paste_B

(Contd. of page 4)

· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	97 °C
· Auto-ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	65 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Particle characteristics	SiO ₂ : Diameter particle structure = 2.5 - 50 nm (TEM, d ₅₀ , number-based) Diameter agglomerate = 5 - 50 μm (laser diffraction dry module, d ₅₀ , volume based)

· 9.2 Other information	
· Appearance:	
· Form:	Pasty
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Water:	33.2 %
· VOC (EC)	0.0 g/l
· Change in condition	
· Evaporation rate	Not determined.

· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void

(Contd. on page 6)

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

Printing date 25.07.2024

Version number 3 (replaces version 2)

Revision: 25.07.2024

Trade name: GC_Fuji_ORTHO_BAND_PASTE_PAK_Paste_B

(Contd. of page 5)

- | | |
|----------------------------------|------|
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | 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.
- **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** Causes serious eye damage.
- **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**
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.
- **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.

(Contd. on page 7)

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

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Trade name: GC_Fuji_ORTHO_BAND_PASTE_PAK_Paste_B

(Contd. of page 6)

- **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 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.

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 hazardous substances

- **Uncleaned packaging:**

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

SECTION 14: Transport information

<ul style="list-style-type: none"> · 14.1 UN number or ID number 	<ul style="list-style-type: none"> · ADR, ADN, IMDG, IATA not regulated
<ul style="list-style-type: none"> · 14.2 UN proper shipping name 	<ul style="list-style-type: none"> · ADR, ADN, IMDG, IATA not regulated
<ul style="list-style-type: none"> · 14.3 Transport hazard class(es) 	<ul style="list-style-type: none"> · ADR, ADN, IMDG, IATA · Class not regulated
<ul style="list-style-type: none"> · 14.4 Packing group 	<ul style="list-style-type: none"> · ADR, IMDG, IATA not regulated
<ul style="list-style-type: none"> · 14.5 Environmental hazards: 	<ul style="list-style-type: none"> · Marine pollutant: No
<ul style="list-style-type: none"> · 14.6 Special precautions for user 	<ul style="list-style-type: none"> · ADR, ADN, IMDG, IATA Not applicable.
<ul style="list-style-type: none"> · 14.7 Maritime transport in bulk according to IMO instruments 	<ul style="list-style-type: none"> · ADR, ADN, IMDG, IATA Not applicable.
<ul style="list-style-type: none"> · UN "Model Regulation": 	<ul style="list-style-type: none"> · ADR, ADN, IMDG, IATA not regulated

EU

(Contd. on page 8)

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

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Trade name: GC_Fuji_ORTHO_BAND_PASTE_PAK_Paste_B

(Contd. of page 7)

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.

· **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**

H318 Causes serious eye damage.

H319 Causes serious eye 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

· **Date of previous version:** 22.07.2022

· **Version number of previous version:** 2

· **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)

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

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

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

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

(Contd. on page 9)

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

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Trade name: GC_Fuji_ORTHO_BAND_PASTE_PAK_Paste_B

(Contd. of page 8)

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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