

Safety data sheet
according to UK REACH

Printing date 22.07.2025

Version number 3 (replaces version 2)

Revision: 22.07.2025

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

· **1.1 Product identifier**

· **Trade name:** GC Fuji ORTHO LC PASTE PAK Automix Paste A

· **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:**

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**

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the GB 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**



GHS07

· **Signal word** Warning

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Trade name: GC_Fuji_ORTHO_LC_PASTE_PAK_Automix_Paste_A

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· **Hazard-determining components of labelling:**

2-hydroxyethyl metacrylate
Urethane Dimethacrylate (UDMA)
Potassium persulfate

· **Hazard statements**

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves / 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.
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.

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:**

CAS: 868-77-9 EINECS: 212-782-2 Index number: 607-124-00-X	2-hydroxyethyl metacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-<25%
CAS: 68909-20-6 EINECS: 272-697-1	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica STOT RE 2, H373, EUH066 Nanoform: set including amorphous nanoforms; surface-treated nanoforms; Spheroidal; amorphous forms; amorphous nanoform	5-<10%
CAS: 1830-78-0 EINECS: 217-388-4	2-Hydroxy-1,3 dimethacryloxypropane Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-<5%
CAS: 72869-86-4 EINECS: 276-957-5 Index number: 607-767-00-6	Urethane Dimethacrylate (UDMA) Aquatic Chronic 2, H411; Skin Sens. 1B, H317	2.5-<5%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Substance with a Community workplace exposure limit. Substance identified as having endocrine disrupting properties (II).	0.5-<1%

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Trade name: GC_Fuji_ORTHO_LC_PASTE_PAK_Automix_Paste_A

CAS: 7727-21-1	Potassium persulfate	(Contd. of page 2)
EINECS: 231-781-8	Ox. Sol. 3, H272; Resp. Sens. 1, H334; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	0.2-<0.5%
Index number: 016-061-00-1		

· **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:**

Immediately wash with water and soap and rinse thoroughly.

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. Then 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 Allergic reactions**

· **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 formation of dust.

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.

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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:**

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**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of dust.

Any unavoidable deposit of dust must be regularly removed.

Avoid contact with the eyes and skin.

· **Information about fire - and explosion protection:**

Protect against electrostatic charges.

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:** Keep container tightly sealed.

· **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:**

128-37-0 Butylated hydroxytoluene

WEL Long-term value: 10 mg/m³

· **DNELs**

128-37-0 Butylated hydroxytoluene

Dermal DNEL dermal 0.5 mg/kg bw/day (man)

Inhalative DNEL inhalation 3.5 mg/m³ (man)

· **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.

Do not inhale dust / smoke / mist.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

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*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**

Solid

· **Colour:**

Light yellow

· **Odour:**

Odourless

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

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

Undetermined.

· **Flammability**

Not determined.

· **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 applicable.

· **Viscosity:**· **Kinematic viscosity**

Not applicable.

· **Dynamic:**

Not applicable.

· **Solubility**· **water:**

Insoluble.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not applicable.

· **Density and/or relative density**· **Density:**

Not determined.

· **Relative density**

Not determined.

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· Vapour density	Not applicable.
· Particle characteristics	SiO ₂ : Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-based) Diameter agglomerate = 5 - 50 nm (laser diffraction dry module, d50, volume based) 68909-20-6 Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica: set including amorphous nanoforms; surface-treated nanoforms; Spheroidal; amorphous forms; amorphous nanoform
· 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.
· Change in condition	
· Evaporation rate	Not applicable.
· 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
· 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.

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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:**

72869-86-4 Urethane Dimethacrylate (UDMA)	
Oral LD50	>5,000 mg/kg (rat female) (OECD 401)
128-37-0 Butylated hydroxytoluene	
Oral LD50	>6,000 mg/kg (rat (f+m)) (OECD 401)

- **Primary irritant effect:**

- **Skin corrosion/irritation** Causes skin irritation.

- **Serious eye damage/irritation** Causes serious eye irritation.

- **Respiratory or skin sensitisation** May cause an allergic skin reaction.

- **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	
128-37-0	Butylated hydroxytoluene
List II	

SECTION 12: Ecological information

- **12.1 Toxicity**

Aquatic toxicity:	
72869-86-4 Urethane Dimethacrylate (UDMA)	
EC50/48h (static)	>1.2 mg/l (daphnia magna) (OECD 202)
128-37-0 Butylated hydroxytoluene	
EC50/48h (static)	0.48 mg/l (daphnia magna) (OECD 202)

- **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.

- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.

- **12.7 Other adverse 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

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

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Poisons Act**

· Regulated explosives precursors	None of the ingredients is listed.
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· Regulated poisons	None of the ingredients is listed.
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· Reportable explosives precursors	None of the ingredients is listed.
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· Reportable poisons	None of the ingredients is listed.
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- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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

SECTION 16: Other information

- **Relevant phrases**

H272 May intensify fire; oxidiser.
 H302 Harmful if swallowed.
 H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 H335 May cause respiratory irritation.
 H373 May cause damage to organs through prolonged or repeated exposure.
 H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.
 H411 Toxic to aquatic life with long lasting effects.
 EUH066 Repeated exposure may cause skin dryness or cracking.

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

- **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
 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)
 DNEL: Derived No-Effect Level (UK REACH)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 Ox. Sol. 3: Oxidizing solids – Category 3
 Acute Tox. 4: Acute toxicity – Category 4
 Skin Irrit. 2: Skin corrosion/irritation – Category 2
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 Resp. Sens. 1: Respiratory sensitisation – Category 1
 Skin Sens. 1: Skin sensitisation – Category 1
 Skin Sens. 1B: Skin sensitisation – Category 1B
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
 STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic 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.

Disclaimer:

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referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

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

· 1.1 Product identifier

· **Trade name:** GC Fuji ORTHO LC PASTE PAK Automix 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:

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**

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 GB 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

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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.

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:**

CAS: 9003-01-4	Polyacrylic acid	Eye Irrit. 2, H319	25-<50%
CAS: 14808-60-7 EINECS: 238-878-4	Quartz	STOT RE 1, H372 substance with a Community workplace exposure limit	10-<25%
CAS: 87-69-4 EINECS: 201-766-0	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.

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*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.***· 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.*

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Safety data sheet according to UK REACH

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Version number 2 (replaces version 1)

Revision: 25.07.2024

Trade name: GC_Fuji_ORTHO_LC_PASTE_PAK_Automix_Paste_B

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- **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.
- **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

WEL	Long-term value: 0.1 * mg/m ³ respirable
-----	--

- **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

GB

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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.
· 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:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· Particle characteristics	SiO ₂ : Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-based) Diameter agglomerate = 5 - 50 µm (laser diffraction dry module, d50, 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:	32.3 %
· 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

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· 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
· 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.
- **Serious eye damage/irritation** Causes serious eye damage.
- **STOT-repeated exposure**
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **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.

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- **vPvB:** Not applicable.
- **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 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even 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.
- **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 · ADR, ADN, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | not regulated |
| <ul style="list-style-type: none"> · 14.4 Packing group · ADR, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · 14.6 Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| <ul style="list-style-type: none"> · UN "Model Regulation": | not regulated |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Poisons Act**
- **Regulated explosives precursors**
- None of the ingredients is listed.

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· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

· **Reportable poisons**

None of the ingredients is listed.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** 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

· **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

· **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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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 19.02.2024

Version number 4 (replaces version 3)

Revision: 19.02.2024

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

1.1 Product identifier

· **Trade name:** **GC Fuji ORTHO CONDITIONER**

· **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:

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**

Eye Dam. 1 H318 Causes serious eye damage.

2.2 Label elements

· **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the GB 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

· **Signal word** Danger

· Hazard statements

H318 Causes serious eye damage.

· Precautionary statements

P280 Wear eye protection / face protection.

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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.*

- **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	10-<25%
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- **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:**

Immediately wash with water and soap and rinse thoroughly.

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.

· **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

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- **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.
Do not allow to penetrate the ground/soil.
- **6.3 Methods and material for containment and cleaning up:**
Use neutralising agent.
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.
- **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:**
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**
- **Appropriate engineering controls** No further data; see section 7.

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- **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:** Light yellow
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** 100 °C
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Auto-ignition temperature:** Undetermined.
- **Decomposition temperature:** Not determined.
- **pH at 20 °C** 1.9
- **Viscosity:**
- **Kinematic viscosity** Not determined.
- **Dynamic:** Not determined.
- **Solubility**
- **water:** Insoluble.
- **Partition coefficient n-octanol/water (log value)** Not determined.

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· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· 9.2 Other information	
· Appearance:	
· Form:	Liquid
· 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:	90.0 %
· 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
· 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.

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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.
- **Serious eye damage/irritation** Causes serious eye damage.
- **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

4247-02-3 Isobutyl 4-hydroxybenzoate

List II; III

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.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (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.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

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

SECTION 14: Transport information

- **14.1 UN number or ID number**
- **ADR, ADN, IMDG, IATA** not regulated

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

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Poisons Act**

· Regulated explosives precursors
None of the ingredients is listed.

· Regulated poisons
None of the ingredients is listed.

· Reportable explosives precursors
None of the ingredients is listed.

· Reportable poisons
None of the ingredients is listed.

- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** 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**
H319 Causes serious eye irritation.
- **Classification according to Regulation (EC) No 1272/2008** Calculation method
- **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
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances

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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

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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