

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

Printing date 09.04.2021

Version number 1

Revision: 09.04.2021

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

- **1.1 Product identifier**
- **Trade name:** *GC Initial IQ-LP ONE/ Enamel Effect, Lustre Paste, Lustre Body*
- **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**
*Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
Repr. 1B H360FD May damage fertility. May damage the unborn child.
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**



GHS08

- **Signal word** *Danger*

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

Cristobalite
diboron trioxide

· **Hazard statements**

H360FD May damage fertility. May damage the unborn child.

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 protective gloves/protective clothing/eye protection/face protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

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 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: 14464-46-1 EINECS: 238-455-4 | Cristobalite STOT RE 1, H372 | 25-<50% |
| CAS: 57-55-6 EINECS: 200-338-0 | Propylene glycol substance with a Community workplace exposure limit | 10-<25% |
| CAS: 1303-86-2 EINECS: 215-125-8 Index number: 005-008-00-8 | diboron trioxide Repr. 1B, H360FD | 5-<10% |
| CAS: 13463-67-7 EINECS: 236-675-5 | titanium dioxide substance with a Community workplace exposure limit | 0.5-<1% |

· **SVHC**

1303-86-2 diboron trioxide

· **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.

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- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
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** 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.
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:**
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** Avoid contact with the eyes and skin.
- **Information about fire - and explosion protection:** No special measures required.

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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:** 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:**

14464-46-1 Cristobalite

WEL Long-term value: 0.1* mg/m³
*repairable dust

57-55-6 Propylene glycol

WEL Long-term value: 474* 10** mg/m³, 150* ppm
*total vapour and particulates **particulates

13463-67-7 titanium dioxide

WEL Long-term value: 10* 4** mg/m³
*total inhalable **respirable

· DNELs

13463-67-7 titanium dioxide

| | | |
|------------|-----------------|----------------------------|
| Inhalative | DNEL inhalation | 10 mg/m ³ (man) |
|------------|-----------------|----------------------------|

- **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.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing

- **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.

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· Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

| | |
|--------------------|------------------------------------|
| · Form: | Pasty |
| · Colour: | According to product specification |
| · Odour: | Characteristic |
| · Odour threshold: | Not determined. |

· pH-value: Not determined.

· Change in condition

| | |
|--|---------------|
| · Melting point/freezing point: | Undetermined. |
| · Initial boiling point and boiling range: | 60 °C |

· Flash point: >100 °C

· Flammability (solid, gas): Not applicable.

· Ignition temperature: Undetermined.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

| | |
|----------|------------|
| · Lower: | 2.6 Vol % |
| · Upper: | 12.6 Vol % |

· Vapour pressure: Not determined.

· Density: Not determined.

2,56 g/cm³
1,18g/ml

· Relative density: Not determined.

· Vapour density: Not determined.

· Evaporation rate: Not determined.

· Solubility in / Miscibility with water:

Insoluble.

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

· Viscosity:

| | |
|--------------|-----------------|
| · Dynamic: | Not determined. |
| · Kinematic: | Not determined. |

· Solvent content:

Organic solvents: ≥20.0 %

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VOC (EC) ≥ 200.0 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 relevant for classification:**

13463-67-7 titanium dioxide

| | | |
|------------|----------|---------------------------------|
| Oral | LD50 | >5,000 mg/kg (mouse) (OECD 420) |
| Inhalative | LC50/4 h | >6.82 mg/l (rat male) |

- **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 (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**
May damage fertility. May damage the unborn child.
- **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.

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.
- **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.

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- **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.
- **Uncleaned packaging:**
- **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 · ADR · IMDG, IATA | 1760 CORROSIVE LIQUID, N.O.S. (POTASSIUM MONOXIDE, cerium trifluoride) 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 · Stowage Code | Not applicable. SW2 Clear of living quarters. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | |
| · ADR · Excepted quantities (EQ) | Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml |
| · IMDG · Excepted quantities (EQ) | Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml |

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· **UN "Model Regulation":** UN 1760 CORROSIVE LIQUID, N.O.S. (POTASSIUM MONOXIDE, CERIUM TRIFLUORIDE), 8, II

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, 30

· **Other regulations, limitations and prohibitive regulations**

· **Substances of very high concern (SVHC) according to REACH, Article 57**

1303-86-2 | diboron trioxide

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

SECTION 16: Other information

· **Relevant phrases**

H360FD May damage fertility. May damage the unborn child.

H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

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

· **Department issuing SDS:** Regulatory affairs

· **Contact:** msds@gc.dental

· **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)

VOC: Volatile Organic Compounds (USA, EU)

DNEL: Derived No-Effect Level (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Repr. 1B: Reproductive toxicity – Category 1B

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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