

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 SPS Stains****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

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.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Dam. 1 H318 Causes serious eye damage.

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

GHS05 GHS08

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· **Signal word** *Danger*· **Hazard-determining components of labelling:**

Cristobalite
diboron trioxide
phosphorus pentoxide
calcium oxide

· **Hazard statements**

H315 Causes skin irritation.
H318 Causes serious eye damage.
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.
P280 Wear protective gloves/protective clothing/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.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P321 Specific treatment (see on this label).
P362+P364 Take off contaminated clothing and wash it before reuse.
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	<i>Cristobalite</i> <i>STOT RE 1, H372</i>	50-<75%
CAS: 1303-86-2 EINECS: 215-125-8 Index number: 005-008-00-8	<i>diboron trioxide</i> <i>Repr. 1B, H360FD</i>	10-<25%
CAS: 1344-28-1 EINECS: 215-691-6	<i>aluminium oxide</i> <i>substance with a Community workplace exposure limit</i>	10-<25%
CAS: 1304-28-5 EINECS: 215-127-9 Index number: 056-002-00-7	<i>barium oxide, obtained by calcining witherite</i> <i>Acute Tox. 4, H302; Acute Tox. 4, H332; Eye Irrit. 2, H319</i>	2.5-<5%
CAS: 1305-78-8 EINECS: 215-138-9	<i>calcium oxide</i> <i>Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H335</i>	1-<2.5%
CAS: 1314-56-3 EINECS: 215-236-1 Index number: 015-010-00-0	<i>phosphorus pentoxide</i> <i>Skin Corr. 1A, H314</i>	1-<2.5%

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CAS: 1314-23-4 EINECS: 215-227-2	zirconium oxide substance with a Community workplace exposure limit	0.5-<1%
CAS: 7758-88-5 EINECS: 231-841-3	cerium trifluoride substance with a Community workplace exposure limit	0.5-<1%
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.

· **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.

If symptoms persist consult doctor.

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, 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.

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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.

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.

Do not allow to penetrate the ground/soil.

· **6.3 Methods and material for containment and cleaning up:**

Pick up mechanically.

Prevent formation of dust.

Dispose of the material collected according to regulations.

· **6.4 Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**

Prevent formation of dust.

Any unavoidable deposit of dust must be regularly removed.

Avoid contact with the eyes and skin.

· **Information about fire - and explosion protection:** Dust can combine with air to form an explosive mixture.

· **7.2 Conditions for safe storage, including any incompatibilities**

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** Store only in unopened original receptacles.

· **Information about storage in one common storage facility:** Store away from foodstuffs.

· **Further information about storage conditions:** None.

· **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

· **8.1 Control parameters**

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

14464-46-1 Cristobalite

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

1303-86-2 diboron trioxide

WEL Short-term value: 20 mg/m³
Long-term value: 10 mg/m³

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1344-28-1 aluminium oxide

WEL Long-term value: $10^* 4^{**}$ mg/m³
*inhalable dust **respirable dust

1304-28-5 barium oxide, obtained by calcining witherite

WEL Long-term value: 0.5 mg/m³
as Ba

1305-78-8 calcium oxide

WEL Short-term value: 4* mg/m³
Long-term value: 2 1* mg/m³
*respirable fraction

1314-56-3 phosphorus pentoxide

WEL Short-term value: 2 mg/m³
Long-term value: 1 mg/m³

1314-23-4 zirconium oxide

WEL Short-term value: 10 mg/m³
Long-term value: 5 mg/m³
as Zr

7758-88-5 cerium trifluoride

WEL Long-term value: 2.5 mg/m³
as F

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)
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· **Additional information:** The lists valid during the making were used as basis.· **8.2 Exposure controls**· **Personal protective equipment:**· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

Do not inhale dust / smoke / mist.

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.

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- **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:**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Solid
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Not determined.

- **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:	Not determined.
Upper:	Not determined.

- **Vapour pressure:** Not applicable.

- **Density:** Not determined.
2,56 g/cm³
1,18g/ml

- **Relative density** Not determined.

- **Vapour density** Not applicable.

- **Evaporation rate** Not applicable.

- **Solubility in / Miscibility with water:** Fully miscible.

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

- **Viscosity:**

Dynamic:	Not applicable.
Kinematic:	Not applicable.

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

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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 together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging:**

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

· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

UN1759

· **14.2 UN proper shipping name**

· **ADR**

1759 CORROSIVE SOLID, N.O.S. (POTASSIUM MONOXIDE, PHOSPHORUS PENTOXIDE)

· **IMDG, IATA**

CORROSIVE SOLID, N.O.S. (POTASSIUM MONOXIDE, PHOSPHORUS PENTOXIDE)

· **14.3 Transport hazard class(es)**

· **ADR**



· **Class**

8 (C10) Corrosive substances.

· **Label**

8

· **IMDG, IATA**



· **Class**

8 Corrosive substances.

· **Label**

8

· **14.4 Packing group**

· **ADR, IMDG, IATA**

II

· **14.5 Environmental hazards:**

Not applicable.

· **14.6 Special precautions for user**

Warning: Corrosive substances.

· **Hazard identification number (Kemler code):**

80

· **EMS Number:**

F-A,S-B

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· Segregation groups	Acids
· Stowage Category	A
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	

· ADR	
· Limited quantities (LQ)	1 kg
· Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 g
	Maximum net quantity per outer packaging: 500 g
· Transport category	2
· Tunnel restriction code	E

· IMDG	
· Limited quantities (LQ)	1 kg
· Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 g
	Maximum net quantity per outer packaging: 500 g
· UN "Model Regulation":	UN 1759 CORROSIVE SOLID, N.O.S. (POTASSIUM MONOXIDE, PHOSPHORUS PENTOXIDE), 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: 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
- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.
- 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

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- **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)

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

Acute Tox. 4: Acute toxicity - oral – Category 4

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

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

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

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

Repr. 1B: Reproductive toxicity – Category 1B

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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