

**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
  - **Information department:** Regulatory affairs
- **1.4 Emergency telephone number:** International: +01-813-248-0585 (ChemTel Inc.)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**

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 labeled according to the CLP regulation.
  - **Exemptions**

The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).
  - **Hazard pictograms**  
  
GHS05 GHS08
  - **Signal word** Danger
  - **Hazard-determining components of labeling:**

Cristobalite  
diboron trioxide  
phosphorus pentoxide  
calcium oxide

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**· 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 characterization: Mixtures****· Description:**

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

**· Dangerous components:**

14464-46-1	Cristobalite STOT RE 1, H372	50-<75%
1303-86-2	diboron trioxide Repr. 1B, H360FD	10-<25%
1304-28-5	barium oxide, obtained by calcining witherite Acute Tox. 4, H302; Acute Tox. 4, H332; Eye Irrit. 2, H319	2.5-<5%
1305-78-8	calcium oxide Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H335	1-<2.5%
1314-56-3	phosphorus pentoxide Skin Corr. 1A, H314	1-<2.5%
7758-88-5	cerium trifluoride	0.5-<1%

**· SVHC**

1303-86-2	diboron trioxide
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**· Additional information:** For the wording of the listed hazard phrases refer to section 16.

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### 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:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire fighting measures that suit the environment.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.  
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **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.

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- **6.3 Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Prevent formation of dust.  
Dispose of the collected material according to regulations.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Prevent formation of dust.  
Any deposit of dust which cannot be avoided must be regularly removed.  
Avoid contact with the eyes and skin.
- **Information about protection against explosions and fires:**  
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 systems:** No further data; see item 7.

- **8.1 Control parameters**

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

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

IOELV	Long-term value: 0.5 mg/m <sup>3</sup> as Ba
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**1305-78-8 calcium oxide**

IOELV	Short-term value: 4 mg/m <sup>3</sup> Long-term value: 1 mg/m <sup>3</sup> Respirable fraction
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**1314-56-3 phosphorus pentoxide**

IOELV	Long-term value: 1 mg/m <sup>3</sup>
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**7758-88-5 cerium trifluoride**

IOELV	Long-term value: 2.5 mg/m <sup>3</sup> as F
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- **DNELs**

**13463-67-7 titanium dioxide**

Inhalative	DNEL inhalation	10 mg/m <sup>3</sup> (man)
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- **Additional information:** The lists that were valid during the creation were used as basis.

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- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures for handling chemicals should be followed.  
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.
- **Breathing equipment:** 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.
- **Eye protection:**



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

· <b>Form:</b>	Solid
· <b>Color:</b>	According to product specification
· <b>Odor:</b>	Characteristic
· <b>Odor threshold:</b>	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not determined.
- **Ignition temperature:** Undetermined.
- **Decomposition temperature:** Not determined.
- **Auto igniting:** Product is not selfigniting.

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· <b>Danger of explosion:</b>	<i>Product does not present an explosion hazard.</i>
· <b>Explosion limits:</b>	
<b>Lower:</b>	<i>Not determined.</i>
<b>Upper:</b>	<i>Not determined.</i>
· <b>Vapor pressure:</b>	<i>Not applicable.</i>
· <b>Density:</b>	<i>Not determined.</i>
	<i>2,56 g/cm<sup>3</sup></i>
	<i>1,18g/ml</i>
· <b>Relative density</b>	<i>Not determined.</i>
· <b>Vapor density</b>	<i>Not applicable.</i>
· <b>Evaporation rate</b>	<i>Not applicable.</i>
· <b>Solubility in / Miscibility with Water:</b>	<i>Fully miscible.</i>
· <b>Partition coefficient (n-octanol/water):</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
<b>Dynamic:</b>	<i>Not applicable.</i>
<b>Kinematic:</b>	<i>Not applicable.</i>
· <b>9.2 Other information</b>	<i>No further relevant information available.</i>

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** *No further relevant information available.*
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **10.3 Possibility of hazardous reactions** *No dangerous reactions known.*
- **10.4 Conditions to avoid** *No further relevant information available.*
- **10.5 Incompatible materials:** *No further relevant information available.*
- **10.6 Hazardous decomposition products:** *No dangerous decomposition products known.*

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:** *Based on available data, the classification criteria are not met.*

· **LD/LC50 values that are relevant for classification:**

**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:**
- **on the skin:**  
*Causes skin irritation.*
- **on the eye:**  
*Causes serious eye damage.*
- **Sensitization:** *Based on available data, the classification criteria are not met.*

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· **Additional toxicological information:**· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**  
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 (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

## SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

## SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN1759

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· **14.2 UN proper shipping name**  
· **DOT** Corrosive solids, n.o.s. (Potassium monoxide, Phosphorus pentoxide)  
· **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· **Segregation groups** Acids· **Stowage Category** A

· **14.7 Transport in bulk according to Annex II of MARPOL73/78 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

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· <b>Excerpted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 500 g
· <b>UN "Model Regulation":</b>	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
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· **Section 355 (extremely hazardous substances):**

1314-56-3	phosphorus pentoxide
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· **Section 313 (Specific toxic chemical listings):**

1344-28-1	aluminium oxide
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1304-28-5	barium oxide, obtained by calcining witherite
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· **Proposition 65**

· **Chemicals known to cause cancer:**

14464-46-1	Cristobalite
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13463-67-7	titanium dioxide
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· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

1303-86-2	diboron trioxide	I (oral)
1304-28-5	barium oxide, obtained by calcining witherite	D, CBD(inh), NL(oral)
1306-38-3	cerium dioxide	II
7758-88-5	cerium trifluoride	II

· **TLV (Threshold Limit Value established by ACGIH)**

14464-46-1	Cristobalite	A2
1344-28-1	aluminium oxide	A4
1304-28-5	barium oxide, obtained by calcining witherite	A4
1314-23-4	zirconium oxide	A4
7758-88-5	cerium trifluoride	A4
13463-67-7	titanium dioxide	A4

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

14464-46-1	Cristobalite	1
1344-28-1	aluminium oxide	2

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13463-67-7	titanium dioxide	3A
· <b>NIOSH-Ca (National Institute for Occupational Safety and Health)</b>		
14464-46-1	Cristobalite	
13463-67-7	titanium dioxide	

- **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**

· <b>Substances of very high concern (SVHC) according to REACH, Article 57</b>		
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

- **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

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

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

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

- ECHA (<http://echa.europa.eu/>)
- EnviChem ([www.echemportal.org](http://www.echemportal.org))

**\* Data compared to the previous version altered.***This version replaces all previous versions.***Disclaimer:**

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