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

Printing date 07.08.2018

Version number 4

Revision: 02.05.2018

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

- · 1.1 Product identifier
- · Trade name: GC Initial Spectrum Stain, Powder
- 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

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. The product is not classified, according to the CLP regulation.
- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008
- Exempt from requirements product regulated as a medical device or an in vitro diagnostic medical device.
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 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: Void
- 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:

No special measures required.

- If symptoms persist consult doctor.
- After inhalation: Take affected persons into fresh air and keep quiet.
- · After skin contact: Immediately rinse with water.
- After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, 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
- \cdot 5.2 Special hazards arising from the substance or mixture
- Formation of toxic gases is possible during heating or in case of fire.
- 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.
- · 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. 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.

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· 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:
- 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
- · 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.
- Wash hands before breaks and at the end of work.
- · 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.
- Eye protection: Safety glasses

9.1 Information on basic physical and General Information	nd chemical properties	
· 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 ra	nge: 2,980 °C	
Flash point:	Not applicable.	

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· 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.	
· Relative density	Not determined.	
· Vapour density	Not applicable.	
· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
water:	Insoluble.	
· Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
· 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: No further relevant information available.
- · 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 (carcinogenity, 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.

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- Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- 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.

- · 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. Contact waste processors for recycling information.

\cdot European waste catalogue

	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing dangerous substances

· Uncleaned packaging:

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

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	not recordered	
	not regulated	
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA		
· Class	not regulated	

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· 14.4 Packing group · ADR, IMDG, IATA	not regulated	
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Transport in bulk according to Ann Marpol and the IBC Code	ex II of Not applicable.	
· UN "Model Regulation":	not regulated	

SECTION 15: Regulatory information

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

SECTION 16: Other information

· 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· Sources

• ECHA (http://echa.europa.eu/)

• EnviChem (www.echemportal.org)

\cdot * Data compared to the previous version altered.

This version replaces all previous versions.

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