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

Printing date 22.03.2023

Version number 2 (replaces version 1)

Revision: 22.03.2023

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

· 1.1 Product identifier

· Trade name: GRADIA_PLUS_SEPARATOR

• 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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H336 May cause drowsiness or dizziness.

· 2.2 Label elements

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

The product is classified and labeled according to the CLP regulation. • *Hazard pictograms*



· Signal word Danger

Hazard-determining components of labeling: isopropyl alcohol
Hazard statements
H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

Precautionary statements
P210
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P261
Avoid breathing dust/fume/gas/mist/vapors/spray
P280
Wear protective gloves/protective clothing/eye protection/face protection.

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75-<90%

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(Contd. of page 1) P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Store locked up.

· 2.3 Other hazards

P405

· 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:

67-63-0 isopropyl alcohol

Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336

• 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: 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, 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.

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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. Keep away from ignition sources 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: *Ensure adequate ventilation.* Absorb liquid components with liquid-binding material. 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 Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols. Avoid contact with the eyes and skin. · Information about protection against explosions and fires: Keep ignition sources away - Do not smoke. Protect against electrostatic charges. Do not spray on a naked flame or any incandescent material. • 7.2 Conditions for safe storage, including any incompatibilities · Storage: • Requirements to be met by storerooms and receptacles: Store in a cool location. Store only in unopened original receptacles. • Information about storage in one common storage facility: Store away from foodstuffs. • Further information about storage conditions: Keep receptacle tightly sealed. Store in cool, dry conditions in well sealed receptacles. Protect from heat and direct sunlight. Store in a cool place. · 7.3 Specific end use(s) No further relevant information available.

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SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Components 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 that were valid during the creation were used as basis.
- · 8.2 Exposure controls
- Additional information about design of technical systems: No further data; see item 7.
- · Personal protective equipment:
- · General protective and hygienic measures:
- The usual precautionary measures for handling chemicals should be followed.
- 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.
- · 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		
· Physical state	Fluid	
· Color:	Clear	
· Odor:	Characteristic	
• Odor threshold:	Not determined.	
• Melting point/Melting range:	Undetermined.	
· Boiling point/Boiling range:	Undetermined.	
· Flammability (solid, gaseous):	Highly flammable.	
Explosion limits:		
· Lower:	2 Vol %	
· Upper:	12 Vol %	

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· Flash point:	13 °C
· Ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· pH-value:	Not determined.
· Viscosity:	
Kinematic:	Not determined.
· Dynamic:	Not determined.
Solubility in / Miscibility with	
· Water:	Insoluble.
• Partition coefficient (n-octanol/water):	Not determined.
· Vapor pressure:	Not determined.
Density and/or relative density	
· Density:	Not determined.
Relative density	Not determined.
· Vapor density	Not determined.
• 9.2 Other information	
· Appearance:	
· Form:	Liquid
Important information on protection of health a	
environment, and on safety.	Due due tie wet eelte enitie e
· Auto igniting:	Product is not selfigniting.
Danger of explosion: Solvent content:	Product does not present an explosion hazard.
	77.5 %
· Organic solvents:	
· VOC (EC) · Change in condition	775.0 g/l
· Evaporation rate	Not determined.
•	ivoi uelei mineu.
Information with regard to physical hazard classes	17 . 1
Explosives	Void
· Flammable gases	Void
Aerosols	Void
• Oxidising gases	Void
Gases under pressure	Void
· Flammable liquids	Highly flammable liquid and vapour.
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 gas	
in contact with water	Void Void
• Oxidising liquids	Void Void
• Oxidising solids	Void Void
• Organic peroxides	Void Void
· Corrosive to metals	
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

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- · 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:

		are relevant for etassification.
67-63-0 is	opropyl alc	cohol
Oral	LD50	4,570 mg/kg (rat (f+m))
Dermal	LD50	13,400 mg/kg (rab)

Inhalative |LC50/4 h| 30 mg/l (rat (f+m))

• on the skin: Based on available data, the classification criteria are not met.

- on the eye: Causes serious eye irritation.
- Sensitization: Based on available data, the classification criteria are not met.
- 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 Based on available data, the classification criteria are not met.
- Specific target organ toxicity single exposure May cause drowsiness or dizziness.
- Specific target organ toxicity repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

• 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 (carcinogenity, 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.
- **vPvB:** Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

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· 12.7 Other adverse effects

- Additional ecological information:
- · General notes:

Water hazard class 3 (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.

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.

· European waste catalogue

18 00 00 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 hazardous substances*

· Uncleaned packagings:

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

14.1 UN-Number		
ADR, IMDG, IATA	UN1219	
14.2 UN proper shipping name		
DOT	Isopropanol mixture	
ADR	1219 ISOPROPYL ALCOHOL mixture	
IMDG, IATA	ISOPROPYL ALCOHOL mixture	
· 14.3 Transport hazard class(es)		
ADR		
· Class	3 (F1) Flammable liquids	
Label	3	
IMDG, IATA		
Class	3 Flammable liquids	
	1	

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14.4 Packing group	
ADR, IMDĞ, IATA	II
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids
Hazard identification number (Kemler code):	33
EMS Number:	F-E,S-D
Stowage Category	В
14.7 Transport in bulk according to Annex II of	of
MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	D/E
IMDG	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 1219 ISOPROPYL ALCOHOL MIXTURE, 3, II

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture · Sara

· Section 355 (extremely hazardous substances):

None of the ingredient is listed.

· Section 313 (Specific toxic chemical listings):

67-63-0 isopropyl alcohol

· Proposition 65

• Chemicals known to cause cancer:

None of the ingredients is listed.

· 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.

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(Contd. of page 8) · Carcinogenic categories · EPA (Environmental Protection Agency) None of the ingredients is listed. · TLV (Threshold Limit Value) 67-63-0 isopropyl alcohol A4· MAK (German Maximum Workplace Concentration) None of the ingredients is listed. · NIOSH-Ca (National Institute for Occupational Safety and Health) None of the ingredients is listed. · Directive 2012/18/EU · Named dangerous substances - ANNEX I None of the ingredients is listed. · Seveso category P5c FLAMMABLE LIQUIDS \cdot Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t • Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t • REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3 DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II None of the ingredients is listed. · REGULATION (EU) 2019/1148 Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3)) None of the ingredients is listed. · Annex II - REPORTABLE EXPLOSIVES PRECURSORS None of the ingredients is listed. · Regulation (EC) No 273/2004 on drug precursors None of the ingredients is listed. Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors 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

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

- · Classification according to Regulation (EC) No 1272/2008 Calculation method
- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- Date of previous version 13.10.2022
- · Version number of previous version: 1
- 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

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(Contd. of page 9) DOT: US Department of Transportation 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 NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health Flam. Liq. 2: Flammable liquids – Category 2 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – 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: The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products 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.