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

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Version number 4 (replaces version 3)

Revision: 02.11.2023

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

· 1.1 Product identifier

· Trade name: G-Multi PRIMER

• 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.

Skin Sens. 1 H317 May cause an allergic skin reaction.

## · 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



· Signal word Danger

Hazard-determining components of labeling:

2,2'-ethylenedioxydiethyl dimethacrylate

2-Propenoic acid, 2-methyl-, polymer with (chloromethyl)oxirane and 4,4-(1-methylethylidene)bisphenol • Hazard statements

H225 Highly flammable liquid and vapour.

H317 May cause an allergic skin reaction.

## · Precautionary statements

P210	<i>Keep away from heat/sparks/open flames/hot surfaces No smoking.</i>
D161	An is the set the set of the set

P261 Avoid breathing dust/fume/gas/mist/vapors/spray

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P272	Contaminated work clothing must not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P35.	3 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/
	shower.
P501	Dispose of contents/container in accordance with local/regional/national/international
	regulations.
· 2 3 Other hazards	-

 $\cdot$  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 d	components:	
64-17-5	ethyl alcohol	90-<100%
	Flam. Liq. 2, H225	
	methacryloyloxydecyl dihydrogen phosphate	1-<2.5%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	1-<2.5%
	Skin Sens. 1, H317	
	2-Propenoic acid, 2-methyl-, polymer with (chloromethyl)oxirane and 4,4-(1-	0.5-<1%
	methylethylidene)bisphenol	
	Eye Dam. 1, H318; Skin Sens. 1, H317	
Additional	<b>reformation</b> . For the wording of the listed hazard physics refer to section 16	

• 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:

Generally the product does not irritate the skin. Immediately wash with water and soap and rinse thoroughly. Seek medical treatment. If skin irritation continues, consult a doctor.

• After eve 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 Allergic reactions

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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.
- · 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
Wear protective equipment. Keep unprotected persons away.
Use respiratory protective device against the effects of fumes/dust/aerosol.
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.
Do not allow to enter sewers/ surface or ground water.
Prevent seepage into sewage system, workpits and cellars.
Dilute with plenty of water.
6.3 Methods and material for containment and cleaning up:
Ensure adequate ventilation.
Allow to evaporate.
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.

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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.

## 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 section 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.

Immediately remove all soiled and contaminated clothing.

## • Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air. Suitable respiratory protective device recommended.

• Protection of hands:

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.



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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Enapustantion	(Contd. of pag
Eye protection:	
Tightly sealed goggles	
SECTION 9: Physical and chemical pr	operties
9.1 Information on basic physical and chemica	l properties
General Information Physical state	Fluid
	Fiuta Colorless
Color:	Alcohol-like
Odor:	
Odor threshold:	Not determined. -114.5 °C
Melting point/Melting range: Boiling point/Boiling range:	-114.5 °C 78 °C
Flammability (solid, gaseous):	Highly flammable.
Explosion limits: Lower:	3.5 Vol %
Lower: Upper:	15 Vol %
Flash point:	13 °C
Auto igniting:	425 °C
Decomposition temperature:	Not determined.
pH-value:	Not determined.
Viscosity:	Not determined.
<i>Kinematic:</i>	Not determined.
Dynamic:	Not determined.
Solubility in / Miscibility with	Not acterminea.
Water at 20 °C:	1.000 g/l
	Insoluble.
Partition coefficient (n-octanol/water):	Not determined.
Vapor pressure at 20 °C:	59 hPa
Density and/or relative density	
Density at 20 °C:	$0.8 \ g/cm^3$
Relative density	Not determined.
Vapor density	Not determined.
9.2 Other information	
Appearance:	
Form:	Liquid
Important information on protection of hea	lth and
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Solvent content:	
Organic solvents:	94.0 %
VOC (EC)	752.0 g/l
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard clas	sses
Explosives	Void

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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	gases	
in contact with water	Void	
Oxidising liquids	Void	
Oxidising solids	Void	
Organic peroxides	Void	
Corrosive to metals	Void	
Desensitised explosives	Void	

## 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.
- $\cdot$  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:

64-17-5 ethyl al	lcohol
------------------	--------

Inhalative LC50/4 h 20,000 mg/l (rat (f+m))

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

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

• Sensitization: May cause an allergic skin reaction.

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

• 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.

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- *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.
- 12.7 Other adverse effects
- 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.

## **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.

14.1 UN-Number ADR, IMDG, IATA	UN1170	
14.2 UN proper shipping name		
DOT	Ethanol mixture	
ADR	1170 ETHANOL SOLUTION mixture	
IMDG, IATA	ETHANOL SOLUTION mixture	

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14.3 Transport hazard class(es)	
ADR	
Class	3 (F1) Flammable liquids
Label	3
IMDG, IATA	
Class	3 Flammable liquids
Label	3
14.4 Packing group	11
ADR, IMDG, IATA	II
14.5 Environmental hazards: Marine pollutant:	No
•	
14.6 Special precautions for user Hazard identification number (Kemler code):	Warning: Flammable liquids 33
EMS Number:	<i>F-E,S-D</i>
Stowage Category	A
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	of Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	
Excepted quantities (EQ)	Code: E2 Maximum not quantity non innon packaging: 20 ml
	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)	
Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 1170 ETHANOL SOLUTION MIXTURE, 3, II
011 Induci Regulation .	ON THE ETHNICL SOLUTION WIATORE, J, II

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## **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):

None of the ingredients is listed.

· 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:

64-17-5 *ethyl alcohol* 

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value)

64-17-5 ethyl alcohol

· MAK (German Maximum Workplace Concentration)

64-17-5 ethyl alcohol

· 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

• 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.

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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. H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

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

· Department issuing SDS: Regulatory affairs

· Contact: msds@gc.dental

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• Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO) 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

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

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

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

*Éye Irrit. 2: Serious eye damage/eye irritation – Category 2* 

Skin Sens. 1: Skin sensitisation – Category 1

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

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