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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: <u>GC Initial IQ-LP ONE/ Enamel Effect, Lustre Paste, Lustre Body</u> • 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 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.

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



· Signal word Danger

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dihoron	trioxide
	statements
	O May damage fertility. May damage the unborn child.
H372	Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
	ionary statements
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P308+F	P313 IF exposed or concerned: Get medical advice/attention.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
2.3 Oth	er hazards
Results	of PBT and vPvB assessment
	ot applicable.
vPvB: N	lot applicable.

· 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	Cristobalite STOT RE 1, H372	25-<50%
CAS: 57-55-6 EINECS: 200-338-0	Propylene glycol substance with a Community workplace exposure limit	10-<25%
CAS: 1303-86-2 EINECS: 215-125-8 Index number: 005-008-00-8	diboron trioxide Repr. 1B, H360FD	5-<10%
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.

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• *After skin contact: Immediately wash with water and soap and rinse thoroughly.*

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, 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.
- 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 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: Absorb liquid components with liquid-binding material. 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 Avoid contact with the eyes and skin.

• Information about fire - and explosion protection: No special measures required.

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- 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 *repirable dust
- 57-55-6 Propylene glycol
- WEL Long-term value: 474* 10** mg/m³, 150* ppm *total vapour and particulates **particulates
- 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/m3 (man)

• 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.
- 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.

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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• Eye protection:

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Tightly sealed goggles

9.1 Information on basic physical and	chemical properties	
General Information		
Appearance: Form:	Dacto	
Form. Colour:	Pasty According to product specification	
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling rang		
Flash point:	>100 °C	
Flammability (solid, gas):	Not applicable.	
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:	2.6 Vol %	
Upper:	12.6 Vol %	
Vapour pressure:	Not determined.	
Density:	Not determined.	
	$2,56 \text{ g/cm}^3$	
	1,18g/ml	
Relative density	Not determined. Not determined.	
Vapour density Evaporation rate	Not determined.	
Solubility in / Miscibility with		
water:	Insoluble.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
Solvent content: Organic solvents:	≥20.0 %	

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VOC (EC) • 9.2 Other information \geq 200.0 g/l 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 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.
- · 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

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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· 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.*

14.1 UN-Number	
ADR, IMDG, IATA	not regulated
14.2 UN proper shipping name	
ADR	1760 CORROSIVE LIQUID, N.O.S. (POTASSIU)
	MONOXIDE, cerium trifluoride)
IMDG, IATA	not regulated
14.3 Transport hazard class(es)	
ADR, ADN, IMDG, IATA	
Class	not regulated
14.4 Packing group	
ADR, IMDG, IATA	not regulated
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Not applicable.
Stowage Code	SW2 Clear of living quarters.
14.7 Transport in bulk according to Ann	ex II of
Marpol and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
IMDG	
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml

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· UN "Model Regulation":

UN 1760 CORROSIVE LIQUID, N.O.S. (POTASSIUM MONOXIDE, CERIUM TRIFLUORIDE), 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: 3, 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

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

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)

- 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 Repr. 1B: Reproductive toxicity – Category 1B
- 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. 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

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limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.



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Printing date 07.08.2018

Version number 2

Revision: 20.01.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: GC Initial IQ/LP-Diluting liquid · 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 \cdot 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. 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.

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Printing date 07.08.2018

Version number 2

Revision: 20.01.2016

Trade name: GC Initial IQ/LP-Diluting liquid

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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:

0 1			
CAS: 57-55-6	Propylene glycol	substance with a Community workplace exposure limit	90-<100%
EINECS: 200-338-0			

· 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:
- 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
- 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.

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Trade name: GC Initial IQ/LP-Diluting liquid

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• 6.3 Methods and material for containment and cleaning up: Absorb liquid components with liquid-binding material. 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 No special precautions are necessary if used correctly. • Information about fire - and explosion protection: No special measures required.

· 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:

57-55-6 Propylene glycol

WEL Long-term value: 474* 10** mg/m³, 150* ppm *total vapour and particulates **particulates

• 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. 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

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hemical properties
1 0000
1 0000
1 0000
According to product specification
Characteristic
Not determined.
Not determined.
Undetermined.
Undetermined.
Not applicable.
Not applicable.
Undetermined.
Not determined.
Product is not selfigniting.
Product does not present an explosion hazard.
2.6 Vol %
12.6 Vol %
Not determined.
Fully miscible.
Not determined.
Not determined.
Not determined.
99.9 %
0.1 %
1,000.0 g/l 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.

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Trade name: GC Initial IQ/LP-Diluting liquid

- 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.
- 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.

· 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)

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Trade name: GC Initial IQ/LP-Diluting liquid

18 01 00 wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 07 chemicals other than those mentioned in 18 01 06

· 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	SECTION	<i>14</i> :	Transport	t in	formation
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Shorifori in Transport injorman	
· 14.1 UN-Number · ADR, ADN, IMDG, IATA	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
· 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 Anne. Marpol and the IBC Code	e x 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

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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) VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent PBT: Persistent, Bioaccumulative and Toxic

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GB

Trade name: GC Initial IQ/LP-Diluting liquid

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

Printing date 03.08.2018

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Version number 2

Revision: 03.05.2018

 1.1 Product identifier Trade name: <u>GC 10 LP NF refresh liquid / 10 Layering-over-Zircon Liner thinner</u> 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 ret. + 32/(0)16/74.10.00 Fax + 32/(0)16/74.10.00 Fax + 32/(0)16/14.026.84 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 Classification of the substance or mixture Classification of the substance or mixture Classification is a Regulation (EC) No 1272/2008 Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device. Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
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· Classification according to Regulation (EC) No 1272/2008 Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
 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. The product is classified and labelled according to the CLP regulation. Hazard pictograms Void Signal word Void Hazard statements H412 Harmful to aquatic life with long lasting effects. Precautionary statements P273 Avoid release to the environment. 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.

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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:
-------------	-------------

Dungerous components.		
CAS: 57-55-6	Propylene glycol	90-<100%
EINECS: 200-338-0	substance with a Community workplace exposure limit	
CAS: 7646-85-7	Zinc chloride	≥0.25-<0.5%
EINECS: 231-592-0	Skin Corr. 1B, H314; Aquatic Acute 1, H400; Aquatic Chronic 1,	
Index number: 030-003-00-2	H410; Acute Tox. 4, H302	

• 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: 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:
- 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.

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SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Remove persons from danger area.
 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:
 Absorb liquid components with liquid-binding material.
 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 No special precautions are necessary if used correctly.

- · Information about fire and explosion protection: No special measures required.
- · 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:

57-55-6 Propylene glycol

WEL Long-term value: 474* 10** mg/m³, 150* ppm *total vapour and particulates **particulates

7646-85-7 Zinc chloride

WEL Short-term value: 2 mg/m³

Long-term value: 1 mg/m³

• 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. Wash hands before breaks and at the end of work.
- Respiratory protection: Suitable respiratory protective device recommended.
- Protection of hands: Protective gloves

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· 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

SECTION 9: Physical and chemical properties

• 9.1 Information on basic physical and cl • General Information	hemical properties
· General Information · Appearance:	
Form:	Fluid
Colour:	According to product specification
· Odour:	Characteristic
• Odour threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	: Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not applicable.
· 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:	2.6 Vol %
Upper:	12.6 Vol %
· Vapour pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	92.0 %
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Trade name: GC IQ LP NF refresh liquid / IQ Layering-over-Zircon Liner thinner

Water: VOC (EC) 0.0 % 920.1 g/l No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

· 9.2 Other information

• 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:

7646-85-7 Zinc chloride

Oral LD50 350 mg/kg (*rat* (*f*+*m*))

· 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.
- 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.
- · Ecotoxical effects:
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:
- Harmful to aquatic organisms

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

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Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground.

· 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.

• 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 dangerous substances*

• Uncleaned packaging:

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

SECTION 14: Transport informat	tion
· 14.1 UN-Number · ADR, ADN, IMDG, IATA	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
· 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 Anno Marpol and the IBC Code	ex II of Not applicable.
· UN "Model Regulation":	not regulated

SECTION 15: Regulatory information

• 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture • REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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

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SECTION 16: Other information

· Relevant phrases

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

- · 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)
- 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
- Acute Tox. 4: Acute toxicity Category 4
- Skin Corr. 1B: Skin corrosion/irritation Category 1B
- Aquatic Acute 1: Hazardous to the aquatic environment acute aquatic hazard Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3

· Sources

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