

Printing date 02/14/2022

Version US-EN-Rev 1

Reviewed on 02/14/2022

- · Product identifier
- · Trade name: GC Initial® IQ Lustre Paste ONE/NF Refresh Liquid
- Relevant identified uses of the substance or mixture and uses advised against Dental material

The product is intended for professional use.

To avoid risks for humans and environment obtain instructions.

- · Application of the substance / the mixture Auxiliary for manufacture of dental prothesis
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

GC America Inc. 3737 W. 127th Street Alsip, IL 60803 USA

SDS.gcamerica@gc.dental

· Information department: Regulatory Affairs

Emergency telephone number:

During normal opening times (Monday–Friday 8:00 AM–5:00 PM Central Time): +1 (708) 597-0900 Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard(s) identification

· Classification of the substance or mixture

The product is not classified, according to the Globally Harmonized System (GHS).

· Additional information:

The information provided is in regards to the toxicity and hazard rating(s) of the individual component(s) in the formulation. The associated risk(s) depends on the route(s) of exposure. The hazard rating system is based entirely on the existence of the risk(s) and does not take into account the likelihood of reduced risk(s) through proper usage and handling.

- · Label elements
- · GHS label elements
- Exempt from labeling medical devices and drugs do not require labeling according to HCS 2012.
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Hazard(s) not otherwise classified (HNOC): None known.
- · Other hazards
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Mixtures

· Description: Mixture of the substances listed below with nonhazardous additions.

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75 – < 100%

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Dangerous components:	
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CAS: 57-55-6 propylene glycol

· Additional information:

Concentrations of dangerous components are expressed in percent by weight (% w/w).

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

4 First-aid measures

· Description of first aid measures

· General information:

No special measures required. If symptoms persist consult doctor.

• After inhalation:

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

- After skin contact: Rinse with warm water. If symptoms persist consult 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.
- Information for doctor:
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire fighting measures that suit the environment.

- For safety reasons unsuitable extinguishing agents: Water with full jet
- Special hazards arising from the substance or mixture
- In case of fire, the following can be released: Carbon monoxide (CO) Carbon dioxide
- · 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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	utions, protective equipment and emergency procedures s from danger area.	
Environmental		
	duct to reach sewage system or any water course.	
Inform respective	e authorities in case of seepage into water course or sewage system	n.
	enetrate the ground/soil.	
	ge into the ground inform responsible authorities. aterial for containment and cleaning up:	
	nponents with liquid-binding material.	
	ollected material according to regulations.	
Reference to ot	her sections	
	r information on safe handling.	
	r information on personal protection equipment.	
	or disposal information. On Criteria for Chemicals	
Protective Action	Criterion (PAC) [.] Protective Action Criteria (PACs) [.] Lower Explosive	≏ Limit (LEL)
	n Criterion (PAC); Protective Action Criteria (PACs); Lower Explosive PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ P	
 * indicates the F ** indicates the I 	PAC value is between 10% and up to 50% of the LEL (10% LEL \leq PPAC value is between 50% and up to 100% of the LEL (50% LEL \leq	PAC < 50% LEL).
* indicates the F ** indicates the I *** indicates the	PAC value is between 10% and up to 50% of the LEL (10% LEL \leq PAC value is between 50% and up to 100% of the LEL (50% LEL \leq PAC value is at 100% or more of the LEL (PAC \geq LEL).	PAC < 50% LEL).
* indicates the F ** indicates the I *** indicates the excerpt from Intr	PAC value is between 10% and up to 50% of the LEL (10% LEL \leq PPAC value is between 50% and up to 100% of the LEL (50% LEL \leq	PAC < 50% LEL).
* indicates the F ** indicates the I *** indicates the excerpt from Intr PAC-1:	PAC value is between 10% and up to 50% of the LEL (10% LEL \leq PAC value is between 50% and up to 100% of the LEL (50% LEL \leq PAC value is at 100% or more of the LEL (PAC \geq LEL). oduction to PAC Table 2 – PAC Rev. 29 – May 2016	PAC < 50% LEL). PAC < 100% LEL
* indicates the F ** indicates the *** indicates the excerpt from Intr PAC-1: CAS: 57-55-6	PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ P PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC value is at 100% or more of the LEL (PAC ≥ LEL). oduction to PAC Table 2 – PAC Rev. 29 – May 2016 propylene glycol	PAC < 50% LEL). PAC < 100% LEL
* indicates the F ** indicates the excerpt from Intr PAC-1: CAS: 57-55-6 CAS: 7631-86-9	PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ P PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC value is at 100% or more of the LEL (PAC ≥ LEL). oduction to PAC Table 2 – PAC Rev. 29 – May 2016 propylene glycol silicon dioxide	PAC < 50% LEL). PAC < 100% LEL 30 mg/m 18 mg/m
* indicates the F ** indicates the excerpt from Intr PAC-1: CAS: 57-55-6 CAS: 7631-86-9 CAS: 7646-85-7	PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ P PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC value is at 100% or more of the LEL (PAC ≥ LEL). oduction to PAC Table 2 – PAC Rev. 29 – May 2016 propylene glycol silicon dioxide	PAC < 50% LEL). PAC < 100% LEL
* indicates the F *** indicates the excerpt from Intr PAC-1: CAS: 57-55-6 CAS: 7631-86-9 CAS: 7646-85-7	PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ P PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC value is at 100% or more of the LEL (PAC ≥ LEL). oduction to PAC Table 2 – PAC Rev. 29 – May 2016 propylene glycol silicon dioxide zinc chloride	PAC < 50% LEL). PAC < 100% LEL 30 mg/m 18 mg/m 2 mg/m ³
* indicates the F ** indicates the excerpt from Intr PAC-1: CAS: 57-55-6 CAS: 7631-86-9 CAS: 7646-85-7 PAC-2: CAS: 57-55-6	PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ P PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC value is at 100% or more of the LEL (PAC ≥ LEL). oduction to PAC Table 2 – PAC Rev. 29 – May 2016 propylene glycol silicon dioxide zinc chloride	PAC < 50% LEL). PAC < 100% LEL 30 mg/m 18 mg/m 2 mg/m ³ 1,300 mg/m
* indicates the F ** indicates the excerpt from Intr PAC-1: CAS: 57-55-6 CAS: 7631-86-9 CAS: 7646-85-7 PAC-2:	PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ P PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC value is at 100% or more of the LEL (PAC ≥ LEL). oduction to PAC Table 2 – PAC Rev. 29 – May 2016 propylene glycol silicon dioxide zinc chloride	PAC < 50% LEL). PAC < 100% LEL 30 mg/m 18 mg/m 2 mg/m ³ 1,300 mg/m 740 mg/m ³
* indicates the F ** indicates the excerpt from Intr PAC-1: CAS: 57-55-6 CAS: 7631-86-9 CAS: 7646-85-7 PAC-2: CAS: 57-55-6	PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ P PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC value is at 100% or more of the LEL (PAC ≥ LEL). oduction to PAC Table 2 – PAC Rev. 29 – May 2016 propylene glycol silicon dioxide propylene glycol silicon dioxide	PAC < 50% LEL). PAC < 100% LEL 30 mg/m 18 mg/m 2 mg/m ³ 1,300 mg/m
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7 Handling and storage

- · Handling:
- Precautions for safe handling Observe instructions for use.
- · Information about protection against explosions and fires: No special measures required.
- · 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: Observe instructions for use / storage.

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• Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see item 7.

- · Control parameters
- Components with limit values that require monitoring at the workplace:
- CAS: 57-55-6 propylene glycol
- WEEL Long-term value: 10 mg/m³
- **Regulatory information** WEEL: Guide to Occupational Exposure Values (AIHA WEELs)
- Additional information: The lists that were valid during the creation were used as basis.
- Exposure controls
- Personal protective equipment:
- General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed. Wash hands before breaks and at the end of work.

• 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:



Safety glasses

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:
 - Form:

Liquid

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Color:	Colorless	
Odor:	Odorless	
Odor threshold:	Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
Flash point:	Not applicable.	
Flammability (solid, gaseous):	Not applicable.	
Ignition temperature:	Undetermined.	
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not self-igniting.	
Danger of explosion:	Not determined.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapor pressure:	Not determined.	
Density:	Not determined.	
Relative density	Not determined.	
Vapor density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
Water:	Soluble.	
Partition coefficient (n-octanol/wa	ter): Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
Solvent content:		
Organic solvents:	92.0 %	
Water:	2.0 %	
VOC content:	92.00 %	
Other information	No further relevant information available.	

10 Stability and reactivity

· Reactivity No further relevant information available.

- · Chemical stability Stable at ambient temperature.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.

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· Hazardous decomposition products:

Carbon dioxide

Carbon monoxide

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:
- CAS: 7646-85-7 zinc chloride
- Oral LD50 350 mg/kg (rat (f+m))

Primary irritant effect:

- on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- Symptoms related to the physical, chemical and toxicological characteristics: No further relevant information available.
- · Subacute to chronic toxicity: No further relevant information available.
- Numerical measures of toxicity: No further relevant information available.

• Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations.

- · Carcinogenic categories
- IARC (International Agency for Research on Cancer) silicon dioxide
 NTP (National Toxicology Program) None of the ingredients is listed.
- · OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

Carcinogenic categories' legend:

IARC Group 1: The agent is carcinogenic to humans.

IARC Group 2A: The agent is probably carcinogenic to humans.

IARC Group 2B: The agent is possibly carcinogenic to humans.

IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.

IARC Group 4: The agent is probably not carcinogenic to humans.

NTP K: Known to be human carcinogen.

NTP R: Reasonably anticipated to be human carcinogen.

• Additional carcinogenic information: No further relevant information available.

- · Repeated dose toxicity. No further relevant information available.
- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
- No further relevant information available. No further relevant information available.
- Germ cell mutagenicity No further relevant information available.
- Carcinogenicity No further relevant information available.
- · Reproductive toxicity No further relevant information available.
- Specific target organ toxicity single exposure No further relevant information available.
- · Specific target organ toxicity repeated exposure No further relevant information available.

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· Aspiration hazard No further relevant information available.

12 Ecological information

- · Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- Mobility in soil No further relevant information available.
- Ecotoxical effects:
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German regulation, AwSV) (Self-assessment): clearly hazardous to water 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.

Harmful to aquatic organisms

- Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- **vPvB:** Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

· Waste treatment methods

- **Recommendation:** Dispose of contents / container in accordance with local / regional / national / international regulations.
- · Uncleaned packagings:
- **Recommendation:** Disposal must be made according to official regulations.
- Recommended cleansing agent: Water, if necessary with cleansing agents.

UN-Number		
DOT, ADR, IMDG, IATA	Not regulated.	
UN proper shipping name DOT, ADR, IMDG, IATA	Not regulated.	
Transport hazard class(es)		
DOT, ADR, ADN, IMDG, IATA		
Class	Not regulated.	
Packing group		
DOT, ADR, IMDG, IATA	Not regulated.	
Environmental hazards:	Not applicable.	

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 Special precautions for user 	Not applicable.
 Transport in bulk according to Annex MARPOL73/78 and the IBC Code 	k II of Not applicable.
· UN "Model Regulation":	Not regulated.

15 Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture
 SARA (Superfund Amendments and Reauthorization Act)

• Section 355 (extremely hazardous substances):

None of the ingredients is listed.

Section 313 (Specific toxic chemical listings):

zinc chloride

• TSCA (Toxic Substances Control Act):

All components have the value ACTIVE.

• Additional information:

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

· Hazardous Air Pollutants

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:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

zinc chloride

· EPA carcinogenic categories' legend:

EPA weight-of-evidence (WoE): official codes and categories from EPA's 1986 guidelines and unofficial, derived codes from EPA's standard hazard descriptors from 1996, 1999, and 2005 guidelines A: human carcinogen (1986)

B1: probable human carcinogen – based on limited evidence of carcinogenicity in humans (1986)

B2: probable human carcinogen – based on sufficient evidence of carcinogenicity in animals (1986) C: possible human carcinogen (1986)

D: not classifiable as to human carcinogenicity (1986)

E: evidence of non-carcinogenicity for humans (1986)

CaH: carcinogenic to humans

CBD: carcinogenic potential cannot be determined

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Trade name: GC Initial® IQ Lustre Paste ONE/NF Refresh Liquid (Contd. of page 8) I: data are inadequate for an assessment of human carcinogenic potential II: inadequate information to assess carcinogenic potential K/L: known/likely human carcinogen L: likely to be carcinogenic to humans NL: not likely to be carcinogenic to humans S: suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential SC: suggestive evidence of carcinogenic potential · TLV (Threshold Limit Value) None of the ingredients is listed. ACGIH carcinogenic categories' legend: A1: confirmed human carcinogen A2: suspected human carcinogen A3: confirmed animal carcinogen with unknown relevance to humans A4: not classifiable as a human carcinogen A5: not suspected as a human carcinogen · NIOSH-Ca (National Institute for Occupational Safety and Health) None of the ingredients is listed. · GHS label elements Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012. · Hazard pictograms Void · Signal word Void · Hazard statements Void · Chemical safety assessment: A Chemical Safety Assessment has not been carried out. **16 Other information** · Department issuing SDS: Regulatory Affairs · Contact: **Regulatory Affairs** Telephone No. +1 (708) 597-0900 SDS.gcamerica@gc.dental · Date of preparation / last revision 02/14/2022 / -Abbreviations and acronyms: GHS: Globally Harmonized System of Classification and Labelling of Chemicals HCS: Hazard Communication Standard (USA) MSDS: Material Safety Data Sheet SDS: Safety Data Sheet ADN: Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways) ECHA: European Chemicals Agency OSHA: Occupational Safety and Health Administration (USA) PAC: Protective Action Criterion (USA) PACs: Protective Action Criteria (USA) HNOC: Hazard Not Otherwise Classified (USA) LEL: Lower Explosive Limit UEL: Upper Explosive Limit OSHA-Ca: Occupational Safety and Health Administration - Carcinogens or potential carcinogens regulated (USA) NIOSH-Ca: National Institute for Occupational Safety and Health - Carcinogen List (USA) NIOSH: National Institute for Occupational Safety and Health (USA) TSCA: Toxic Substances Control Act (USA) AwSV: Verordnung über Anlagen zum Ümgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances that are hazardous to water) (Germany) NOEC: No Observed Effect Concentration ADR: Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road) (Contd. on page 10)

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IMDG Code: International Maritime Dangerous Goods Code	(
DOT: Department of Transportation (USA)	
IATA: International Air Transport Association	
ACGIH: American Conference of Governmental Industrial Hygienists 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	
TLV: Threshold Limit Value	
PEL: Permissible Exposure Limit REL: Recommended Exposure Limit	
· Sources	
Manufacturers' MSDSs/SDSs	
OSHA (https://www.osha.gov/dts/chemicalsampling/toc/chmcas.html)	
PubChem (https://pubchem.ncbi.nlm.nih.gov/)	
• ECHA (http://echa.europa.eu/)	
EnviChem (www.echemportal.org)	
· Notes:	
CAS Registry Number® is a registered trademark of the American Chemical Society.	
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· Disclaimer:	
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