## **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

071350941

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071350875 071350883 071350891 071350909 071350917 071350925 071350933 071432384 071432392



## Safety Data Sheet

according to HPR, Schedule 1

Printing date 08/08/2021

Version CA-EN-Rev 1

Reviewed on 08/08/2021

- · Product identifier
- Trade name: GC Initial<sup>™</sup> LiSi Block (Shades: HT and LT: A1, A2, A3 & B1) (Size: 14)

· 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 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 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 classification and labeling devices and drugs are not regulated according to WHMIS 2015.
- · Hazard pictograms Void
- · Signal word Void
- Hazard statements Void

### **3** Composition/Information on ingredients

- · Chemical characterization: Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.
- · Dangerous components: Void

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#### · 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 No further relevant information available.
- 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.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Remove persons from danger area.
- 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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- Methods and material for containment and cleaning up: Pick up mechanically.
- Dispose of the collected material according to regulations.

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.

## 7 Handling and storage

- · Handling:
- Precautions for safe handling
   Observe instructions for use.
   Prevent formation of dust.
   Any deposit of dust which cannot be avoided must be regularly removed.
- Information about protection against explosions and fires: No further relevant information available.
- · 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.
- · 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:

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.
- · Exposure controls
- Personal protective equipment:
- General protective and hygienic measures: The usual precautionary measures for handling chemicals should be followed. Do not inhale dust / smoke / mist. Wash hands before breaks and at the end of work.
- Breathing equipment:



Suitable respiratory protective device recommended.

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• 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

Information on basic physical and	chemical properties
General Information	
Appearance:	
Form:	Solid
Color:	Tooth color
Odor: Odor threshold:	Odorless Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	920 °C
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Product is not flammable.
Ignition temperature:	Not applicable.
Decomposition temperature:	Not determined.
Auto igniting:	Product is not self-igniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not applicable.
Density at 20 °C:	2.5 g/cm <sup>3</sup>
· Relative density	Not determined.

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Vapor density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water:	Insoluble.	
Partition coefficient (n-octanol/w	ater): Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
Solvent content:		
Organic solvents:	0 %	
Solids content:	100.0 %	
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.
- · Hazardous decomposition products: No dangerous decomposition products known.

## **11** Toxicological information

- · Information on toxicological effects
- Acute toxicity:
- · LD/LC50 values that are relevant for classification: No further relevant information available.
- · 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)

#### None of the ingredients is listed.

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	(*
<ul> <li>NTP (National Toxicology Program)</li> </ul>	
None of the ingredients is listed.	
· Carcinogenic categories' legend:	
IADC Crown 1: The agent is parajagapia to hymotra	

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.
- 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.
- Additional ecological information:
- · General notes:

Water hazard class 1 (German regulation, AwSV) (Self-assessment): slightly hazardous to water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- 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.

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· Uncleaned packagings:

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

4 Transport information		
· UN-Number · DOT/TDG, ADR, IMDG, IATA	Not regulated.	
<ul> <li>UN proper shipping name</li> <li>DOT/TDG, ADR, IMDG, IATA</li> </ul>	Not regulated.	
· Transport hazard class(es)		
<sup>·</sup> DOT, ADR, ADN, IMDG, IATA <sup>·</sup> Class	Not regulated.	
<ul> <li>Packing group</li> <li>DOT/TDG, ADR, IMDG, IATA</li> </ul>	Not regulated.	
· Environmental hazards:	Not applicable.	
· Special precautions for user	Not applicable.	
<ul> <li>Transport in bulk according to Anne» MARPOL73/78 and the IBC Code</li> </ul>	x II of Not applicable.	
· UN "Model Regulation":	Not regulated.	

## **15 Regulatory information**

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

· Canadian substance listings:

· Canadian Domestic Substances List (DSL)

All ingredients are listed.

#### · Canadian Non-Domestic Substances List (NDSL)

None of the ingredients is listed.

#### · 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).

• Canadian Ingredient Disclosure list (limit 0.1%)

None of the ingredients is listed.

#### · Canadian Ingredient Disclosure list (limit 1%)

None of the ingredients is listed.

• GHS label elements Exempt from classification and labeling – devices and drugs are not regulated according to WHMIS 2015.

· Hazard pictograms Void

- · Signal word Void
- · Hazard statements Void

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· 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 the latest revision of the safety data sheet 08/08/2021 / - 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) TDG: Transportation of Dangerous Goods (Canada) LEL: Lower Explosive Limit UEL: Upper Explosive Limit AwSV: Verordnung über Anlagen zum Umgang 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) HPR: Hazardous Products Regulations (Canada) IMDG Code: International Maritime Dangerous Goods Code DOT: Department of Transportation (USA) IATA: International Air Transport Association CAS: Chemical Abstracts Service (division of the American Chemical Society) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Sources 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. CHEMTREC® is a registered service mark of the American Chemistry Council, Inc. 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.

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