SAFETY DATA SHEETS

This SDS packet was issued with item:

071162866

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

071162700 071162718 071162726 071162734 071162742 071162759 071162767 071162775 071162783 071162809 071162817 071162825 071162833 071162841 071162858 071162924 071162940

Safety Data Sheet
acc. to OSHA HCS 29 CFR 1910.1200

Printing date 07/03/2019 Version US-EN-Rev 1 Reviewed on 07/03/2019

1 Identification

· **Product identifier**

· **Trade name:** EQUIA Forte HT Fil (Powder, Shades: A1, A2, A3, A3.5, B1, B2, B3, and C4)

· **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** Dental filling material

· **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 not otherwise classified (HNOC):**
None known.

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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Trade name: EQUIA Forte HT Fil (Powder, Shades: A1, A2, A3, A3.5, B1, B2, B3, and C4)

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3 Composition/information on ingredients

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

· **Dangerous components:**		
CAS: 9003-01-4	poly(acrylic acid)	2.5 – < 5%

· **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).

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:**
Generally the product does not irritate the skin.
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**
Formation of toxic gases is possible during heating or in case of fire.
No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** Wear self-contained respiratory protective device.

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· **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.
· **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.
· **Protective Action Criteria for Chemicals**
Protective Action Criterion (PAC); Protective Action Criteria (PACs); Lower Explosive Limit (LEL)
* indicates the PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ PAC < 50% LEL).
** indicates the PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC < 100% LEL).
*** indicates the PAC value is at 100% or more of the LEL (PAC ≥ LEL).
excerpt from Introduction to PAC Table 2 – PAC Rev. 29 – May 2016

· **PAC-1:**		
	silane**	71 mg/m³
CAS: 20344-49-4	iron hydroxide oxide	24 mg/m³
	colorant**	15 mg/m³
CAS: 1317-61-9	triiron tetraoxide	21 mg/m³

· **PAC-2:**		
	silane**	780 mg/m³
CAS: 20344-49-4	iron hydroxide oxide	260 mg/m³
	colorant**	360 mg/m³
CAS: 1317-61-9	triiron tetraoxide	230 mg/m³

· **PAC-3:**		
	silane**	4,700 mg/m³
CAS: 20344-49-4	iron hydroxide oxide	1,600 mg/m³
	colorant**	2,200 mg/m³
CAS: 1317-61-9	triiron tetraoxide	1,400 mg/m³

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.

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Safety Data Sheet
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Trade name: EQUIA Forte HT Fil (Powder, Shades: A1, A2, A3, A3.5, B1, B2, B3, and C4)

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· **Information about protection against explosions and fires:**
Dust can combine with air to form an explosive mixture.

· **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.

· **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:**
Manufacturing sites:
Wear safety glasses with side shields (or goggles).
Distribution, Workplace, and Household Settings:
No special protective equipment required

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Trade name: EQUIA Forte HT Fil (Powder, Shades: A1, A2, A3, A3.5, B1, B2, B3, and C4)

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Powder
Color:	According to product specification
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not determined.
· **Ignition temperature:**	Undetermined.
· **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:**	Not determined.
· **Relative density**	Not determined.
· **Vapor density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with**	
Water:	Insoluble.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· **Solvent content:**	
VOC content:	0.00 %
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.

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Trade name: EQUIA Forte HT Fil (Powder, Shades: A1, A2, A3, A3.5, B1, B2, B3, and C4)

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· **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.

· **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)**	
poly(acrylic acid)	3
colorant**	3

· **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.
· **Repeated dose toxicity.** No further relevant information available.
· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
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.

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Trade name: EQUIA Forte HT Fil (Powder, Shades: A1, A2, A3, A3.5, B1, B2, B3, and C4)

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· **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.

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

14 Transport information

· **UN-Number** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **DOT, ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)** · **DOT, ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **DOT, ADR, IMDG, IATA**	Void
· **Environmental hazards:** · **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Void

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.

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Trade name: EQUIA Forte HT Fil (Powder, Shades: A1, A2, A3, A3.5, B1, B2, B3, and C4)

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· **Section 313 (Specific toxic chemical listings):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

poly(acrylic acid)	ACTIVE
silane**	ACTIVE
iron hydroxide oxide	ACTIVE
colorant**	ACTIVE
triiron tetraoxide	ACTIVE

· **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)**
None of the ingredients is listed.

· **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
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 established by ACGIH)**

colorant**	A4

· **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

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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** 07/03/2019 / -
· **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 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)
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)
• TOXNET (http://toxnet.nlm.nih.gov/)
• ECHA (http://echa.europa.eu/)

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• EnviChem (www.echemportal.org)

· **Notes:**
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