

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/12/2021

Version US-EN-Rev 1

Reviewed on 11/12/2021

1 Identification

- **Product identifier**
- **Trade name:** EXA Advanced (Monophase) (Base) (Normal Set / Fast Set, Cartridge/Tube)
- **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 impression 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**

Eye Irrit. 2A H319 Causes serious eye irritation.
- **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.

Avoid using this product with patients having known silicone allergies.
- **Label elements**
- **GHS label elements**

Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

- **Signal word** Warning
- **Hazard statements**

Causes serious eye irritation.
- **Precautionary statements**

Wash thoroughly after handling.
Wear eye protection / face protection.

(Contd. on page 2)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/12/2021

Version US-EN-Rev 1

Reviewed on 11/12/2021

Trade name: EXA Advanced (Monophase) (Base) (Normal Set / Fast Set, Cartridge/Tube)

(Contd. of page 1)

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

- **Hazard(s) not otherwise classified (HNOC):** None known.
- **Additional information:**
3 % of the mixture consists of component(s) of unknown toxicity.
- **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.

- **Dangerous components:**

CAS: 112926-00-8	silicon dioxide, amorphous (gel or precipitated)	50 – < 75%
	polyethylene glycol derivative**	5 – < 10%

- **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:**
Immediately remove any clothing soiled by the product.
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:**
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.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

(Contd. on page 3)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/12/2021

Version US-EN-Rev 1

Reviewed on 11/12/2021

Trade name: EXA Advanced (Monophase) (Base) (Normal Set / Fast Set, Cartridge/Tube)

(Contd. of page 2)

- **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.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **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.
- **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
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:**

CAS: 112926-00-8	silicon dioxide, amorphous (gel or precipitated)	18 mg/m ³
CAS: 68083-19-2	vinyl dimethylpolysiloxane	48 mg/m ³
	polyethylene glycol derivative**	43 mg/m ³
	colorant**	15 mg/m ³
CAS: 68037-59-2	methylhydrogen dimethylpolysiloxane	30 mg/m ³

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/12/2021

Version US-EN-Rev 1

Reviewed on 11/12/2021

Trade name: EXA Advanced (Monophase) (Base) (Normal Set / Fast Set, Cartridge/Tube)

(Contd. of page 3)

· PAC-2:		
CAS: 112926-00-8	silicon dioxide, amorphous (gel or precipitated)	200 mg/m ³
CAS: 68083-19-2	vinyl dimethylpolysiloxane	530 mg/m ³
	polyethylene glycol derivative**	470 mg/m ³
	colorant**	360 mg/m ³
CAS: 68037-59-2	methylhydrogen dimethylpolysiloxane	330 mg/m ³
· PAC-3:		
CAS: 112926-00-8	silicon dioxide, amorphous (gel or precipitated)	1,200 mg/m ³
CAS: 68083-19-2	vinyl dimethylpolysiloxane	3,200 mg/m ³
	polyethylene glycol derivative**	5,400 mg/m ³
	colorant**	2,200 mg/m ³
CAS: 68037-59-2	methylhydrogen dimethylpolysiloxane	2,000 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Observe instructions for use.
Avoid contact with the eyes and skin.
- **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.
- **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.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
Immediately remove all soiled and contaminated clothing.

(Contd. on page 5)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/12/2021

Version US-EN-Rev 1

Reviewed on 11/12/2021

Trade name: EXA Advanced (Monophase) (Base) (Normal Set / Fast Set, Cartridge/Tube)

(Contd. of page 4)

· **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:	Pasty
· Color:	Pale purple
· 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:** Not applicable.

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not self-igniting.

· **Danger of explosion:** Not determined.

· **Explosion limits:**

· **Lower:** Not determined.

(Contd. on page 6)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/12/2021

Version US-EN-Rev 1

Reviewed on 11/12/2021

Trade name: EXA Advanced (Monophase) (Base) (Normal Set / Fast Set, Cartridge/Tube)

(Contd. of page 5)

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:	Insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0 %
VOC content:	0.00 %
Solids content:	54.0 %
· 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:**
Carbon dioxide
Carbon monoxide

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:** 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 ATEmix is calculated because ingredients of the mixture with LD50 or LC50 values are not considered relevant because of low concentration, a less severe acute toxicity category, or both. (ATEmix is the acute toxicity estimate of the mixture.)

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/12/2021

Version US-EN-Rev 1

Reviewed on 11/12/2021

Trade name: EXA Advanced (Monophase) (Base) (Normal Set / Fast Set, Cartridge/Tube)

(Contd. of page 6)

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

silicon dioxide, amorphous (gel or precipitated)	3
colorant**	3
C.I. Pigment Blue 28	2B

- **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.

- **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 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.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/12/2021

Version US-EN-Rev 1

Reviewed on 11/12/2021

Trade name: EXA Advanced (Monophase) (Base) (Normal Set / Fast Set, Cartridge/Tube)

(Contd. of page 7)

- **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, 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. |
| · 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": | 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):**

polyethylene glycol derivative**

C.I. Pigment Blue 28

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

vinyl dimethylpolysiloxane

ACTIVE

polyethylene glycol derivative**

ACTIVE

colorant**

ACTIVE

C.I. Pigment Blue 28

ACTIVE

(Contd. on page 9)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/12/2021

Version US-EN-Rev 1

Reviewed on 11/12/2021

Trade name: EXA Advanced (Monophase) (Base) (Normal Set / Fast Set, Cartridge/Tube)

(Contd. of page 8)

methylhydrogen dimethylpolysiloxane

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

CAS: 1345-16-0 | C.I. Pigment Blue 28

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)

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

A5: not suspected as a human carcinogen

NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

(Contd. on page 10)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/12/2021

Version US-EN-Rev 1

Reviewed on 11/12/2021

Trade name: EXA Advanced (Monophase) (Base) (Normal Set / Fast Set, Cartridge/Tube)

(Contd. of page 9)

- **GHS label elements**

Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.
The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



- **Signal word** Warning

- **Hazard statements**

Causes serious eye irritation.

- **Precautionary statements**

Wash thoroughly after handling.

Wear eye protection / face protection.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

- **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** 11/12/2021 / -

- **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)

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

(Contd. on page 11)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/12/2021

Version US-EN-Rev 1

Reviewed on 11/12/2021

Trade name: EXA Advanced (Monophase) (Base) (Normal Set / Fast Set, Cartridge/Tube)

(Contd. of page 10)

PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

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. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

US