

SAFETY DATA SHEETS

This SDS packet was issued with item:

072043438

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

072039642 072043404 072043412 072043420 072043446 073259033 073259041 073259058 073259892

SECTION 1 - SOURCE/IDENTITY/USE INFORMATION**MANUFACTURER**

GC AMERICA INC.

3737 West 127th St.

Alsip, Illinois, 60803

Telephone: 708-597-0900

Hours: Mon.- Fri. 8:00 am. - 5:00 pm. C.S.T.

Transportation Emergency No. 800-424-9300

COMMON NAME: EXAFLEX BASE: INJECTION/REGULAR/MONOPHASE/HEAVY BODY**EXAMIX BASE: INJECTION/REGULAR/MONOPHASE/HEAVY BODY - CARTRIDGE**

EXAMIX NDS BASE: INJECTION/REGULAR/MONOPHASE/HEAVY BODY - CARTRIDGE

EXAFAST NDS BASE: INJECTION/REGULAR/MONOPHASE/HEAVY BODY – CARTRIDGE

CHEMICAL NAME: N.A.**PRODUCT USE:** Dental Impression Material

The following information is provided with regard to the toxicity and hazards the pure components present in this portion of the unmixed two paste system

SECTION 2 - HAZARDOUS INGREDIENTS/IDENTITY INFORMATION

COMPONENT	C.A.S.	EXPOSURE LIMITS	LD50/LC50	%
Silica-Amorphous	112926-00-8	PEL = 10.0 mg/m ³ TLV/TWA = 10.0 mg/m ³ (as dust) (ACGIH)	N.E.	40-45
Vinyl Dimethyl Poly - Dimethyl Siloxane	68083-19-2	N.E.	N.E.	40-60
Dimethyl- methylhydrogenpolysiloxane	68037-59-2	N.E.	N.E.	5

SECTION 3 - PHYSICAL/CHEMICAL PROPERTIES**BOILING POINT:** 160°C**VAPOR PRESSURE:** 100/50°C**VAPOR DENSITY:** 2.56**SOLUBILITY IN WATER:** Insoluble**COEFFICIENT OF OIL/WATER DISTRIBUTION:** N.E.**SPECIFIC GRAVITY:** (H₂O=1) 1.35g/cm³**MELTING POINT:** N.E.**EVAPORATION RATE:** N.E.**ODOR THRESHOLD:** N.E.**APPEARANCE AND ODOR:** Odorless paste**SECTION 4 - FIRE AND EXPLOSION DATA****FLASH POINT:** Not Flammable per ASTM D92**FLAMMABLE LIMITS:** N.A.**EXTINGUISHING MEDIA:** Dry Chemical, Carbon Dioxide, Alcohol Foam**SPECIAL FIRE FIGHTING PROCEDURES:** Water is not effective medium. Firefighters should wear self contained breathing apparatus and full protective clothing.**UNUSUAL FIRE AND EXPLOSION HAZARDS:** Irritating and/or toxic aerosols or gases may be present.**HAZARDOUS COMBUSTION PRODUCTS:** Carbon Dioxide, Carbon Monoxide, Sulfur Hydrogen Sulfide**SECTION 5 - REACTIVITY DATA****STABILITY:** Stable ☒Unstable ☐**POLYMERIZATION:** Will Not Occur ☒Will Occur ☐**CONDITIONS TO AVOID:** High temperatures (> 121°C); open flames**INCOMPATIBILITY (Materials to Avoid):** Strong acids, bases, oxidizers.**HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:** N.E.

SECTION 6 - HEALTH HAZARD DATA and FIRST AID INFORMATION

	YES	NO	NE	NA	NTP	IARC	OSHA	OTHER
MUTAGENIC AFFECTS		X						
TERATOGENIC AFFECTS		X						
REPRODUCTIVE TOXIN		X						
CARCINOGENICITY	X (as silica dust)					X		
SENSITIZER		X						

ROUTES OF ENTRY: Inhalation ☒ Skin ☒ Ingestion ☒

HEALTH HAZARD (Acute and Chronic): Breathing vapor generated from this product may be irritating to the eyes, nose and throat.

SIGNS AND SYMPTOMS OF OVEREXPOSURE: Headaches

CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: N.E.

EMERGENCY FIRST AID PROCEDURES:

INHALATION: Remove to fresh air if irritation develops

EYES: Flush with large volumes of water, consult a physician if irritation develops.

SKIN: Wash thoroughly with soap and water

INGESTION: Do not induce vomiting. Dilute by drinking several glasses of water. Seek medical attention.

SECTION 7 - PRECAUTIONS FOR SAFE HANDLING AND USE

IN CASE OF RELEASE OR SPILL: Absorb with inert material; transfer to container for disposal

WASTE DISPOSAL METHOD: In accordance with Local and Federal Regulations.

STORAGE, HANDLING, AND SPECIAL PRECAUTIONS: Store at normal room temperature in a well ventilated area

SECTION 8 - CONTROL MEASURES

RESPIRATORY PROTECTION: N.A.

VENTILATION: Local Exhaust: Recommended Mechanical: N.E. Special: N.E. Other: N.E.

PROTECTIVE GLOVES: Synthetic/Vinyl Gloves

EYE PROTECTION: Safety glasses or goggles

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N.E.

WORK/HYGIENIC PRACTICE: N.E.

SECTION 9 - PREPARATION INFORMATION

This data is supplied to comply with OSHA Hazard Communication Standard 29 CFR 1910,1200 and W.H.M.I.S. CPR

DATE: 09 January 2006

REVIEWED: 20 February 2012

N.A. = NOT APPLICABLE

N.E. = NOT ESTABLISHED

The information herein is given in good faith but no warranty expressed or implied is made.

FIRE - 0

TOXICITY - 1

NFPA
REACTIVITY - 1

SPECIAL -



Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

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Version US-EN-Rev 1

Reviewed on 02/24/2015

1 Identification

- **Product identifier**
- **Trade name:** EXAMIX NDS (Catalyst, Descriptions: Heavy Body, Injection Type, Monophase, and Regular Type)
- **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.com
- **Information department:** Regulatory Affairs
- **Emergency telephone number:**
During normal opening times (Mon.-Fri. 8:00 AM-5:00 PM CST): +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. 2B H320 Causes 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.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms** Void
- **Signal word** Warning
- **Hazard statements**
Causes eye irritation.
- **Precautionary statements**
Wash thoroughly after handling.
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.

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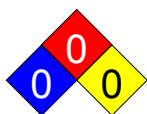
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Trade name: EXAMIX NDS (Catalyst, Descriptions: Heavy Body, Injection Type, Monophase, and Regular Type)

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- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

- **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:** Void
- **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:**
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.

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- **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.
- **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.

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.
- **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:**
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.
- **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:	According to product specification
- **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.

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· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor 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:	0.0 %
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:** Irritating effect.
- **Sensitization:** No sensitizing effects known.

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· **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	3
iron(III) oxide	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.

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 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

· **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:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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- **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": | - |

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 ingredient is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

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

vinyl dimethylpolysiloxane

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

iron(III) oxide

A4

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

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

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- **Hazard pictograms** Void
- **Signal word** Warning
- **Hazard statements**
Causes eye irritation.
- **Precautionary statements**
Wash thoroughly after handling.
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 MSDS:** Regulatory Affairs
- **Contact:**
Regulatory Affairs
Telephone No. +1 (708) 597-0900
sds@gcamerica.com
- **Date of preparation / last revision** 02/24/2015 / -
- **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)
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
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Eye Irrit. 2B: Serious eye damage/eye irritation, Hazard Category 2B
- **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/>)
 - 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.
- *** Data compared to the previous version altered.** This version replaces all previous versions.
- **Disclaimer:**
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