

SAFETY DATA SHEETS

This SDS packet was issued with item:

072054633

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).

072054625

MS003651

GRADIA CORE - BASE
MATERIAL SAFETY DATA SHEET

Page 1 of 2

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

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: GRADIA CORE - Base**CHEMICAL NAME:** N.A.**PRODUCT USE:** Dual-cured composite resin used for restoration, core build-up and post cementation.

The following information is provided with regard to the toxicity and hazards the pure components present in this product.

SECTION 2 - HAZARDOUS INGREDIENTS/IDENTITY INFORMATION

Component	C.A.S.	Exposure Limits	LD50/LC50	%
Fluoro-alumino-silicate glass (fumed/amorphous)	Not Listed	N.E.	N.E.	70-75
Methacrylic acid ester		N.E.	N.E.	20-30
Silicon dioxide	7631-86-9	N.E.	N.E.	1-5
Photo initiator		N.E.	N.E.	Trace
Inhibitor		N.E.	N.E.	Trace
Pigment		N.E.	N.E.	Trace

SECTION 3 - PHYSICAL/CHEMICAL PROPERTIES

BOILING POINT:	1537°C	SPECIFIC GRAVITY:	N.E.
VAPOR PRESSURE:	N.E.	MELTING POINT:	N.E.
VAPOR DENSITY:	N.E.	EVAPORATION RATE:	N.E.
SOLUBILITY IN WATER:	Soluble	ODOR THRESHOLD:	N.E.
COEFFICIENT OF OIL/WATER DISTRIBUTION:	N.E.	APPEARANCE AND ODOR:	Paste

SECTION 4 - FIRE AND EXPLOSION DATA

FLASH POINT: N.A. **FLAMMABLE LIMITS:** N.A.
EXTINGUISHING MEDIA: CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
SPECIAL FIRE FIGHTING PROCEDURES: N.A.
UNUSUAL FIRE AND EXPLOSION HAZARDS: Product does not present an explosion hazard.
HAZARDOUS COMBUSTION PRODUCTS: N.A.

SECTION 5 - REACTIVITY DATA

STABILITY: Stable ☒ Unstable ☐
POLYMERIZATION: Will Not Occur ☒ Will Occur ☐
CONDITIONS TO AVOID:
INCOMPATIBILITY (Materials To Avoid): None
HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: No dangerous decomposition products known.

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						
SENSITIZER	X							



MS003651

GRADIA CORE - BASE

Page 2 of 2

SECTION 6 - HEALTH HAZARD DATA and FIRST AID INFORMATION - continuedROUTES OF ENTRY: Inhalation ☒ Skin ☒ Ingestion ☐**HEALTH HAZARD (Acute And Chronic):** Causes serious eye irritation. Causes skin irritation.**SIGNS AND SYMPTOMS OF OVEREXPOSURE:** May cause an allergic skin reaction.**EMERGENCY FIRST AID PROCEDURES:****INHALATION:** Remove to fresh air and keep at rest in a position comfortable for breathing. Seek medical attention if symptoms persist.**EYE CONTACT:** Flush eyes with water for several minutes. Seek medical attention if irritation persists.**SKIN CONTACT:** Flush skin with plenty of soap and water and rinse thoroughly. Seek medical attention if irritation persists.**INGESTION:** Call a poison control center or doctor if you feel ill.**SECTION 7 - PRECAUTIONS FOR SAFE HANDLING AND USE****IN CASE OF RELEASE OR SPILL:** Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust.).**WASTE DISPOSAL METHOD:** Do not allow product to reach sewer system, surface or ground water. Dispose of waste in accordance with local, state and federal regulations. Contaminated work clothing should not be allowed out of the workplace.**STORAGE, HANDLING, AND SPECIAL PRECAUTIONS:** Store at room temperature in a well-ventilated place. Keep container tightly sealed when not in use.**SECTION 8 - CONTROL MEASURES****RESPIRATORY PROTECTION:** In case of intensive or long exposure, use self-contained respiratory protective device.**VENTILATION:** Local Exhaust ☒ Mechanical: ☐ Special: ☐ Other: ☐**PROTECTIVE GLOVES:** Recommended.**EYE PROTECTION:** Tightly sealed goggles.**OTHER PROTECTIVE CLOTHING OR EQUIPMENT:** Eye wash station.**WORK/HYGIENIC PRACTICE:** Observe good hygienic work practices. Keep away from food, beverages and feed. Immediately remove all contaminated clothing.**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:** 01 June 2009**REVISED:** 22 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****NFPA
REACTIVITY****SPECIAL -**



Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/24/2015

Version US-EN-Rev 1


Reviewed on 02/20/2015

1 Identification

- **Product identifier**
- **Trade name:** GRADIA CORE (Base, Shade: Universal)
- **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.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**
Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **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**

GHS08
- **Signal word** Danger
- **Hazard-determining components of labeling:**
urethane dimethacrylate (UDMA)
dimethacrylate component**
iron(III) oxide
- **Hazard statements**
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(Contd. on page 2)

USA

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/24/2015

Version US-EN-Rev 1

Reviewed on 02/20/2015

Trade name: GRADIA CORE (Base, Shade: Universal)

(Contd. of page 1)

May cause an allergic skin reaction.

Precautionary statements

Contaminated work clothing must not be allowed out of the workplace.

[In case of inadequate ventilation] wear respiratory protection.

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

If experiencing respiratory symptoms: Call a poison center/doctor.

Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:

2.5 % of the mixture consists of component(s) of unknown toxicity.

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

Health = 1

Fire = 1

Reactivity = 1

HMIS-ratings (scale 0 - 4)

Health = 1

Fire = 1

Reactivity = 1

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:**

72869-86-4	urethane dimethacrylate (UDMA)	10-20%
	dimethacrylate component**	1-5%
	dimethacrylate**	1-5%
1309-37-1	iron(III) oxide	< 0.5%

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:**

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.

(Contd. on page 3)

USA

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/24/2015

Version US-EN-Rev 1

Reviewed on 02/20/2015

Trade name: GRADIA CORE (Base, Shade: Universal)

(Contd. of page 2)

- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
Seek medical treatment.
- **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** Allergic reactions
- **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:**
Ensure adequate ventilation.
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.

— USA —

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/24/2015

Version US-EN-Rev 1

Reviewed on 02/20/2015

Trade name: GRADIA CORE (Base, Shade: Universal)

(Contd. of page 3)

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
 - Observe instructions for use.
 - Ensure good ventilation/exhaustion at the workplace.
 - Do not inhale dust / smoke / mist.
 - Prevent formation of aerosols.
 - 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.
- **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

— USA —

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/24/2015

Version US-EN-Rev 1

Reviewed on 02/20/2015

Trade name: GRADIA CORE (Base, Shade: Universal)

(Contd. of page 4)

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Pasty
Color:	White
Odor:	Odorless
Odor threshold:	Not determined.

pH-value:	Not determined.
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- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

Flash point:	> 150 °C (> 302 °F)
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Flammability (solid, gaseous):	Not applicable.
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Ignition temperature:	Undetermined.
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Decomposition temperature:	Not determined.
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Auto igniting:	Product is not selfigniting.
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Danger of explosion:	Product does not present an explosion hazard.
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- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

Vapor pressure:	Not determined.
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Density:	Not determined.
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Relative density	Not determined.
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Vapour density	Not determined.
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Evaporation rate	Not determined.
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- **Solubility in / Miscibility with**

Water:	Insoluble.
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Partition coefficient (n-octanol/water):	Not determined.
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- **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

- **Solvent content:**

Organic solvents:	0.0 %
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Solids content:	100.0 %
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Other information	No further relevant information available.
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10 Stability and reactivity

- **Reactivity** No further relevant information available.

- **Chemical stability** Stable at ambient temperature.

(Contd. on page 6)

USA

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/24/2015

Version US-EN-Rev 1

Reviewed on 02/20/2015

Trade name: GRADIA CORE (Base, Shade: Universal)

(Contd. of page 5)

- **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:**
Sensitization possible through inhalation.
Sensitization possible through skin contact.
- **Additional toxicological information:**
- **Carcinogenic categories**

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

silicon dioxide, amorphous	3
iron(III) oxide	3
titanium dioxide	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.

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

(Contd. on page 7)

USA

Safety Data Sheet

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Printing date 02/24/2015

Version US-EN-Rev 1

Reviewed on 02/20/2015

Trade name: GRADIA CORE (Base, Shade: Universal)

(Contd. of page 6)

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.

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.

(Contd. on page 8)

USA

Safety Data Sheet

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Printing date 02/24/2015

Version US-EN-Rev 1

Reviewed on 02/20/2015

Trade name: GRADIA CORE (Base, Shade: Universal)

(Contd. of page 7)

· TSCA (Toxic Substances Control Act):

glass, oxide, chemicals
urethane dimethacrylate (UDMA)
dimethacrylate component**
dimethacrylate**
silane**
magnesium oxide
iron(III) oxide
synergist**
catalyst**

· Carcinogenic categories
· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

magnesium oxide	A4
iron(III) oxide	A4
titanium dioxide	A4

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

titanium dioxide

· GHS label elements

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

· Hazard pictograms


GHS08

· Signal word Danger

· Hazard-determining components of labeling:

urethane dimethacrylate (UDMA)
 dimethacrylate component**
 iron(III) oxide

· Hazard statements

May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 May cause an allergic skin reaction.

· Precautionary statements

Contaminated work clothing must not be allowed out of the workplace.
 [In case of inadequate ventilation] wear respiratory protection.
 Avoid breathing dust/fume/gas/mist/vapors/spray
 Wear protective gloves.
 If experiencing respiratory symptoms: Call a poison center/doctor.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

USA

(Contd. on page 9)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/24/2015

Version US-EN-Rev 1

Reviewed on 02/20/2015

Trade name: GRADIA CORE (Base, Shade: Universal)

(Contd. of page 8)

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
Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
- **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:**
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