

CPS 3010 G

1. PRODUCT AND COMPANY IDENTIFICATION

Company

Arkema Inc. 900 First Avenue King of Prussia, Pennsylvania 19406

Sartomer

Customer Service Telephone Number: (800) SARTOMER

(Monday through Friday, 8:00 AM to 5:00 PM EST)

Emergency Information

Transportation: CHEMTREC: (800) 424-9300

(24 hrs., 7 days a week)

Medical: Rocky Mountain Poison Center: (866) 767-5089

(24 hrs., 7 days a week)

Product Information

Product name: CPS 3010 G

Synonyms: Proprietary Resin formulation

Molecular formula: Mixture Chemical family: acrylates

Product use: 3D printing resins

2. HAZARDS IDENTIFICATION

Emergency Overview

Color: Clear - colourless

Physical state: liquid
Odor: acrylic-like

*Classification of the substance or mixture:

Skin corrosion, Category 1C, H314 Serious eye damage, Category 1, H318 Skin sensitisation, Category 1, H317 Acute aquatic toxicity, Category 1, H400 Chronic aquatic toxicity, Category 1, H410

*For the full text of the H-Statements mentioned in this Section, see Section 16.



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GHS-Labelling

Hazard pictograms:







Signal word: Danger

Hazard statements:

H314: Causes severe skin burns and eye damage.

H317: May cause an allergic skin reaction.

H410: Very toxic to aquatic life with long lasting effects.

Supplemental Hazard Statements:

Processing may release vapors and/or fumes which cause eye, skin and respiratory tract irritation.

Precautionary statements:

Prevention:

P261: Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

P264: Wash skin thoroughly after handling.

P272: Contaminated work clothing should not be allowed out of the workplace.

P273: Avoid release to the environment.

P280: Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response

P301 + P330 + P331 : IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303 + P361 + P353 : IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.

P304 + P340 : IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing. P310 : Immediately call a POISON CENTER/doctor.

P333 + P313 : If skin irritation or rash occurs: Get medical advice/ attention.

P363: Wash contaminated clothing before reuse.

P391: Collect spillage.

Storage:

P405: Store locked up.

Disposal:

P501 : Dispose of contents or container to an approved waste disposal plant.

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Supplemental information:

Potential Health Effects:

If swallowed, may cause severe irritation and injury to the mouth, throat and digestive tract. Possible cross sensitization with other acrylates and methacrylates. Effects due to processing releases or residual monomer: Irritating to eyes, respiratory system and skin.

Prolonged or repeated exposure may cause: headache, nausea, drowsiness, weakness, (severity of effects depends on extent of exposure).

Other:

This product may release fume and/or vapor of variable composition depending on processing time and temperature.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**	
2-Propenoic acid, 1,6-hexanediyl ester	13048-33-4	>= 60 - < 80 %	H315, H319, H317, H400, H411	
Polythiol	Proprietary*	>= 10 - < 20 %	H302, H317, H400, H410	
Methacrylate ester	Proprietary*	>= 5 - < 10 %	H314, H318, H317	
Photoinitiator	Proprietary*	>= 1 - < 5 %	H411, H317	

^{*}The specific chemical identity is withheld because it is trade secret information of Arkema Inc.

4. FIRST AID MEASURES			
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^{**}For the full text of the H-Statements mentioned in this Section, see Section 16.

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4.1. Description of necessary first-aid measures:

Inhalation:

If inhaled, remove victim to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Skin:

In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eyes:

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately.

Ingestion:

If swallowed, DO NOT induce vomiting. Get medical attention immediately. If victim is fully conscious, give a cupful of water. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms/effects, acute and delayed:

For most important symptoms and effects (acute and delayed), see Section 2 (Hazard Statements and Supplemental Information if applicable) and Section 11 (Toxicology Information) of this SDS.

4.3. Indication of immediate medical attention and special treatment needed, if necessary:

Unless otherwise noted in Notes to Physician, no specific treatment noted; treat symptomatically.

5. FIREFIGHTING MEASURES

Extinguishing media (suitable):

Water spray, Carbon dioxide (CO2), Foam, Dry chemical

Protective equipment:

Fire fighters and others who may be exposed to products of combustion should wear full fire fighting turn out gear (full Bunker Gear) and self-contained breathing apparatus (pressure demand / NIOSH approved or equivalent).

Further firefighting advice:

Fight fire from a protected location.

Cool closed containers exposed to fire with water spray.

Closed containers of this material may explode when subjected to heat from surrounding fire.

Do not allow run-off from fire fighting to enter drains or water courses.

Fire fighting equipment should be thoroughly decontaminated after use.

Fire and explosion hazards:

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When burned, the following hazardous products of combustion can occur:

Carbon oxides

sulfur oxides

phosphorous oxides

Silicone compounds

Nitrogen oxides (NOx)

Amines

Formaldehyde

Hazardous organic compounds

Polymerization is exothermic and can degenerate into an uncontrolled reaction.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, Emergency procedures, Methods and materials for containment/clean-up:

Prevent further leakage or spillage if you can do so without risk. Evacuate area of all unnecessary personnel. Ventilate the area. Avoid generation of vapors. Contain and collect spillage with non-combustible absorbent material such as clean sand, earth, diatomaceous earth or non-acidic clay and place into suitable properly labeled containers for prompt disposal. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits.

Protective equipment:

Appropriate personal protective equipment is set forth in Section 8.

7. HANDLING AND STORAGE

Handling

General information on handling:

Do not taste or swallow.

Do not get in eyes, on skin, or on clothing.

Do not breathe vapor or mist.

Keep container tightly closed.

Use only with adequate ventilation.

Wash thoroughly after handling.

Emptied container retains vapor and product residue.

Observe all labeled safeguards until container is cleaned, reconditioned or destroyed.

Storage

General information on storage conditions:

Keep in a dry, cool place. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Store out of direct sunlight in a cool well-ventilated place. Keep stabilizer levels constant to avoid explosive polymerization. An air space is required above the liquid in all containers; avoid storage under an oxygen-free atmosphere.

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Storage stability - Remarks:

Inhibitor levels should be maintained. The typical shelf-life for this product is 6 months.

Storage incompatibility - General:

Store separate from: Strong oxidizing agents Strong reducing agents Free radical generators Inert gas Oxygen scavenger. Peroxides Strong alkalies

Temperature tolerance - Do not store below:

32 °F (0 °C)

Temperature tolerance - Do not store above:

100 °F (38 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

2-Propenoic acid, 1,6-hexanediyl ester (13048-33-4)

US. OARS. WEELs Workplace Environmental Exposure Level Guide, as amended

Time weighted average 0.11 ppm (1 mg/m3)

Remarks: Listed

Only those components with exposure limits are printed in this section. Limits with skin contact designation above have skin contact effect. Air sampling alone is insufficient to accurately quantitate exposure. Measures to prevent significant cutaneous absorption may be required. Limits with a sensitizer designation above mean that exposure to this material may cause allergic reactions.

Engineering controls:

Investigate engineering techniques to reduce exposures below airborne exposure limits or to otherwise reduce exposures. Provide ventilation if necessary to minimize exposures or to control exposure levels to below airborne exposure limits (if applicable see above). If practical, use local mechanical exhaust ventilation at sources of air contamination such as open process equipment.

Respiratory protection:

Do not breathe vapor or mist. Where airborne exposure is likely or airborne exposure limits are exceeded (if applicable, see above), use NIOSH approved respiratory protection equipment appropriate to the material and/or its components. Full facepiece equipment is recommended and, if used, replaces need for face shield and/or chemical goggles. Consult respirator manufacturer to determine appropriate type equipment for a given

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application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure or where exposure limit may be significantly exceeded, use an approved full face positive-pressure, self-contained breathing apparatus or positive-pressure airline with auxiliary self-contained air supply. Respiratory protection programs must comply with 29 CFR § 1910.134.

Skin protection:

Wear appropriate chemical resistant protective clothing and chemical resistant gloves to prevent skin contact. Consult glove manufacturer to determine appropriate type glove material for given application. Avoid natural rubber gloves. Wear chemical goggles, a face shield, and chemical resistant clothing such as a rubber apron when splashing may occur. Rinse immediately if skin is contaminated. Remove contaminated clothing immediately and wash before reuse. Clean protective equipment before reuse. Provide a safety shower at any location where skin contact can occur. Wash thoroughly after handling.

Eye protection:

Where there is potential for eye contact, wear a face shield, chemical goggles, and have eye flushing equipment immediately available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: Clear - colourless

Physical state: liquid

Odor: acrylic-like

Odor threshold: No data available.

Flash point $> 230 \, ^{\circ}\text{F} \, (110 \, ^{\circ}\text{C})$

Auto-ignition

temperature:

No data available.

Lower flammable limit

(LFL):

No data available.

Upper flammable limit

(UFL):

No data available.

pH: No data available.

Density: No data available.

Specific Gravity (Relative

density):

No data available

Vapor pressure: No data available.

Vapor density: No data available.

Boiling point/boiling No data available.

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range:

Melting point/range: No data available.

Freezing point: No data available.

Evaporation rate: No data available.

Solubility in water: No data available.

Viscosity, dynamic: No data available.

Oil/water partition

coefficient:

No data available.

Thermal decomposition: No data available.

Flammability: See GHS Classification in Section 2 if applicable

10. STABILITY AND REACTIVITY

Stability:

This material is chemically stable under normal and anticipated storage, handling and processing conditions. However, this material can undergo hazardous polymerization.

Hazardous reactions:

Hazardous polymerisation may occur.

Polymerization is exothermic and can degenerate into an uncontrolled reaction.

Materials to avoid:

Strong reducing agents Free radical generators

Inert gas

Oxygen scavenger.

Peroxides

Strong oxidizing agents

Strong alkalies

Conditions / hazards to avoid:

This material polymerizes exothermically in the presence of heat, contamination, oxygen free atmosphere, free radicals, peroxides and inhibitor depletion liberating heat. Avoid direct sunlight. Do NOT expose to ultraviolet light.

Hazardous decomposition products:

Thermal decomposition giving flammable and toxic products:

Carbon oxides Acrylates Methacrylates Nitrogen oxides (NOx) Amines

sulfur oxides

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phosphorous oxides Silicone compounds Formaldehyde Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

Data on this material and/or its components are summarized below.

Data for CPS 3010 G

Acute toxicity

Oral:

Acute toxicity estimate = 3,679 mg/kg.

Dermal:

Acute toxicity estimate = 4,746 mg/kg.

Data for 2-Propenoic acid, 1,6-hexanediyl ester (13048-33-4)

Acute toxicity

Oral:

Practically nontoxic. (rat) LD50 > 5,000 mg/kg.

Dermal:

May be harmful in contact with skin. (rabbit) LD50 = 3,650 mg/kg.

Inhalation:

No deaths occurred. (rat) 7 h LC50 > 0.41 mg/l. (vapor)

Skin Irritation:

Causes skin irritation. (rabbit) (4 h)

Eye Irritation:

Causes serious eye irritation. (rabbit)

Skin Sensitization:

May cause an allergic skin reaction. Guinea pig maximization test. Skin allergy was observed. (Strong sensitizer)

Repeated dose toxicity

Repeated oral administration to rat / affected organ(s): liver, Stomach / signs: changes in organ structure or function, changes in organ weights, clinical chemistry changes, reduced body weight

Genotoxicity

Assessment in Vitro:

No genetic changes were observed in laboratory tests using: bacteria, animal cells

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Developmental toxicity

Reproductive/Developmental Effects Screening Assay. Oral (rat) / No birth defects were observed.

Reproductive effects

Reproductive/Developmental Effects Screening Assay. Oral (rat) / No toxicity to reproduction.

Other information

Possible cross sensitization with other acrylates and methacrylates.

Human experience

Skin contact:

Skin allergy was observed. (based on reports of occupational exposure to workers) (studied using human volunteers) (subjects with dermatitis or eczema)

Data for Polythiol (Proprietary)

Acute toxicity

Oral:

Harmful if swallowed. (rat) LD50 > 300 mg/kg.

Inhalation:

No deaths occurred. (rat) 4 h LC0 = 3.4 mg/l. (dust/mist)

Skin Irritation:

Not irritating. (rabbit)

Eye Irritation:

Not irritating. (rabbit)

Skin Sensitization:

May cause an allergic skin reaction. Guinea pig maximization test. Skin allergy was observed. (Strong sensitizer)

Repeated dose toxicity

Subchronic oral administration to rat / affected organ(s): forestomach / signs: Local irritation, changes in organ structure or function

Genotoxicity

Assessment in Vitro:

No genetic changes were observed in laboratory tests using: bacteria, animal cells

Developmental toxicity

Exposure during pregnancy. oral (rat) / No birth defects were observed.

Data for Methacrylate ester (Proprietary)

Acute toxicity

Oral:

May be harmful if swallowed. (rat) LD50 > 2,000 mg/kg.

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Skin Irritation:

Causes severe skin burns. (rabbit) (4 h)

Not irritating. (rabbit) (3 min)

Eye Irritation:

Causes serious eye damage. (rabbit)

Skin Sensitization:

May cause allergic skin reaction. LLNA: Local Lymph Node Assay. (mouse) Skin allergy was observed.

Repeated dose toxicity

Subchronic oral administration to rat / No adverse systemic effects reported.

Genotoxicity

Assessment in Vitro:

No genetic changes were observed in laboratory tests using: animal cells, bacteria, human cells

Developmental toxicity

Exposure during pregnancy. oral (rat) / No birth defects were observed.

Data for Photoinitiator (Proprietary)

Acute toxicity

Oral:

Practically nontoxic. (rat) LD50 > 5,000 mg/kg.

Dermal:

No deaths occurred. (rat) LD0 > 2,000 mg/kg.

Skin Irritation:

Not irritating. (rabbit) (4 h)

Eye Irritation:

Not irritating. (rabbit)

Skin Sensitization:

May cause an allergic skin reaction. LLNA: Local Lymph Node Assay. (mouse) Skin allergy was observed.

Repeated dose toxicity

Repeated exposure oral administration to rat / No adverse effects reported.

Genotoxicity

Assessment in Vitro:

No genetic changes were observed in laboratory tests using: animal cells, bacteria

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12. ECOLOGICAL INFORMATION

Chemical Fate and Pathway

Data on this material and/or its components are summarized below.

Data for 2-Propenoic acid, 1,6-hexanediyl ester (13048-33-4)

Biodegradation:

Readily biodegradable. (28 d) biodegradation 60 - 70 %

Octanol Water Partition Coefficient:

log Pow: = 2.81, at 77 °F (25 °C)

Data for Polythiol (Proprietary)

Biodegradation:

Not readily biodegradable. (28 d) biodegradation 26 %

Octanol Water Partition Coefficient:

log Pow: = 2.8

Data for Methacrylate ester (Proprietary)

Biodegradation:

Readily biodegradable. (28 d) biodegradation 93.1 %

Octanol Water Partition Coefficient:

log Pow: 1 - 2.7, at 86 °F (30 °C) pH = 7

Data for Photoinitiator (Proprietary)

Stability in water:

114 h (86 °F (30 °C)) (@pH 7)

Biodegradation:

Not readily biodegradable. (28 d) Water < 10 %

Octanol Water Partition Coefficient:

log Pow: = 2.91, at 77 °F (25 °C) 4.4

Ecotoxicology

Data on this material and/or its components are summarized below.

Data for 2-Propenoic acid, 1,6-hexanediyl ester (13048-33-4)

Aquatic toxicity data:

Very toxic to fish. Oryzias latipes (Japanese medaka) 96 h LC50 = 0.38 mg/l

Aquatic invertebrates:

Toxic. Daphnia magna (Water flea) 48 h EC50 = 2.7 mg/l

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Algae:

Toxic. Selenastrum capricornutum (green algae) 72 h EC50 = 2.33 mg/l

Microorganisms:

Activated sludge 30 min EC50 (Respiration inhibition) = 270 mg/l

Chronic toxicity to fish:

Toxic. Oryzias latipes (Japanese medaka) 39 d NOEC = 0.072 mg/l

Chronic toxicity to aquatic invertebrates:

Harmful. Daphnia magna (Water flea) 21 d NOEC 0.14 mg/l

Chronic toxicity to aquatic plants:

Harmful. Desmodesmus subspicatus (green algae) 72 h NOEC (growth rate) 0.9 mg/l

Data for Polythiol (Proprietary)

Aquatic toxicity data:

Very toxic. Oncorhynchus mykiss (rainbow trout) 96 h LC50 = 0.034 mg/l

Aquatic invertebrates:

No effect up to the limit of solubility. Daphnia magna (Water flea) 48 h EC50 > 0.35 mg/l

Algae:

No effect up to the limit of solubility. Desmodesmus subspicatus (green algae) 72 h ErC50 > 0.12 mg/l

Microorganisms:

Respiration inhibition / Activated sludge 28 d EC0 = 23.9 mg/l

Chronic toxicity to aquatic plants:

No effect up to the limit of solubility. Desmodesmus subspicatus (green algae) 72 h NOEC r = 0.12 mg/l

Data for Methacrylate ester (Proprietary)

Aquatic toxicity data:

Practically nontoxic. Oncorhynchus mykiss (rainbow trout) 96 h LC50 > 112 mg/l

Aquatic invertebrates:

Harmful. Daphnia magna (Water flea) 48 h EC50 = 68 mg/l

Algae:

Practically nontoxic. Pseudokirchneriella subcapitata (green algae) 72 h ErC50 > 120 mg/l

Chronic toxicity to aquatic plants:

Practically nontoxic. Pseudokirchneriella subcapitata (green algae) 72 d NOEC r = 30 mg/l

Data for Photoinitiator (Proprietary)

Aquatic toxicity data:

Toxic. Brachydanio rerio (zebrafish) 96 h LC50 = 1.89 mg/l

Aquatic invertebrates:



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Toxic. Daphnia magna (Water flea) 48 h EC50 = 2.26 mg/l

Algae:

Toxic. Pseudokirchneriella subcapitata 72 h EC50 = 1.01 mg/l

Microorganisms:

Respiration inhibition / Activated sludge 3 h EC20 > 1,000 mg/l

13. DISPOSAL CONSIDERATIONS

Waste disposal:

Disposal via incineration is recommended. Dispose of in accordance with federal, state and local regulations. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits. Note: Chemical additions to, processing of, or otherwise altering this material may make this waste management information incomplete, inaccurate, or otherwise inappropriate. Furthermore, state and local waste disposal requirements may be more restrictive or otherwise different from federal laws and regulations.

Take appropriate measures to prevent release to the environment.

14. TRANSPORT INFORMATION

US Department of Transportation (DOT)

UN Number : 1760

Proper shipping name : Corrosive liquids, n.o.s.

Technical name : (Methacrylate ester, 1,6 Hexanediol Diacrylate)

Class : 8
Packaging group : III
Marine pollutant : yes

International Maritime Dangerous Goods Code (IMDG)

UN Number : 1760

Proper shipping name : CORROSIVE LIQUID, N.O.S.

Technical name : (METHACRYLATE ESTER, 1,6 HEXANEDIOL DIACRYLATE)

Class : 8
Packaging group : III
Marine pollutant : yes

Flash point : $> 230 \,^{\circ}\text{F} \, (110 \,^{\circ}\text{C})$

15. REGULATORY INFORMATION

Chemical Inventory Status

US. Toxic Substances Control Act

TSCA

The components of this product are all on

the TSCA Inventory.

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Canadian Domestic Substances List (DSL)

DSL

This product contains one or several

components that are not on the Canadian

DSL nor NDSL lists.

China. Inventory of Existing Chemical Substances in IECSC (CN) Conforms to

China (IECSC)

Japan. ENCS - Existing and New Chemical ENCS (JP) Does not conform

Substances Inventory

Japan. ISHL - Inventory of Chemical Substances ISHL (JP) Does not conform

Korea. Korean Existing Chemicals Inventory (KECI) KECI (KR) Conforms to

Philippines Inventory of Chemicals and Chemical PICCS (PH) Does not conform Substances (PICCS)

Australia Inventory of Chemical Substances (AICS)

AICS

Does not conform

United States - Federal Regulations

SARA Title III - Section 302 Extremely Hazardous Chemicals:

The components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.

SARA Title III - Section 311/312 Hazard Categories:

Reactivity Hazard, Acute Health Hazard

SARA Title III - Section 313 Toxic Chemicals:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):

Chemical name CAS-No. Reportable quantity

Phosphoric acid 7664-38-2 5000 lbs

United States - State Regulations



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New Jersey Right to Know

No components are subject to the New Jersey Right to Know Act.

Pennsylvania Right to Know

<u>Chemical name</u>	CAS-No.
2-Propenoic acid, 1,6-hexanediyl ester	13048-33-4

Polythiol Proprietary

Methacrylate ester Proprietary

Phosphoric acid 7664-38-2

2-Propenoic acid 79-10-7

1,4-Benzenediol 123-31-9

Benzene, methyl- 108-88-3

Pennsylvania Right to Know - Environmentally Hazardous Substance(s)

<u>Chemical name</u> <u>CAS-No.</u>

 Phosphoric acid
 7664-38-2

 2-Propenoic acid
 79-10-7

 1,4-Benzenediol
 123-31-9

 Benzene, methyl 108-88-3

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Chemical nameCAS-No.Benzene, methyl-108-88-3

16. OTHER INFORMATION





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Full text of H-Statements referred to under sections 2 and 3.

- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- H411 Toxic to aquatic life with long lasting effects.

Latest Revision(s):

 Reference number:
 200020055

 Date of Revision:
 02/17/2021

 Date Printed:
 02/17/2021

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Arkema has implemented a Medical Policy regarding the use of Arkema products in Medical Devices applications that are in contact with the body or circulating bodily fluids (http://www.arkema.com/en/social-responsibility/responsible-product-management/medical-device-policy/index.html) Arkema has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by Arkema for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, Arkema strictly prohibits the use of any Arkema products in Medical Device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. The Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices, and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices.

It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade Arkema products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements (FDA or other national drug agencies). It is the sole responsibility of the manufacturer of the medical device to conduct all necessary tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance obligations. Any decision regarding the appropriateness of a particular Arkema material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.

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