

SARET® SR500

1. PRODUCT AND COMPANY IDENTIFICATION

<u>Company</u>			
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		
Medical:	(24 hrs., 7 days a week) Rocky Mountain Poison Center: (866) 767-5089 (24 hrs., 7 days a week)		
Product Information			
Product name: Synonyms: Molecular formula: Chemical family: Product use:	SARET® SR500 SARET® CROSSLINKING AGENT Complex mixture Mixture Sealant, Rubber products		

2. HAZARDS IDENTIFICATION

Emergency Overview

Color:dark amberPhysical state:liquidOdor:acrylic-like

*Classification of the substance or mixture:

Skin sensitisation, Category 1, H317 Carcinogenicity, Category 2, H351 Chronic aquatic toxicity, Category 2, H411

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

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Hazard statements:

H317 : May cause an allergic skin reaction.

- H351 : Suspected of causing cancer.
- H411 : 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:

- P201 : Obtain special instructions before use.
- P202 : Do not handle until all safety precautions have been read and understood.
- P261 : Avoid breathing gas/mist/vapours/spray.
- P272 : Contaminated work clothing should not be allowed out of the workplace.
- P273 : Avoid release to the environment.
- P280 : Wear protective gloves.
- P281 : Use personal protective equipment as required.

Response:

P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.

- P308 + P313 : IF exposed or concerned: Get medical advice/ attention.
- 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/ container to an approved waste disposal plant.

Supplemental information:

Potential Health Effects:

Effects due to processing releases: Irritating to eyes, respiratory system and skin. Prolonged or repeated exposure may cause: headache, drowsiness, nausea, weakness, (severity of effects depends on extent of exposure).

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Other:

This product may release fume and/or vapor of variable composition depending on processing time and temperature. Possible cross sensitization with other acrylates and methacrylates.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
2-Propenoic acid, 2-methyl-, 2-ethyl-2- [[(2-methyl-1-oxo-2- propenyl)oxy]methyl]-1,3-propanediyl ester	3290-92-4	<= 87 %	H411
2-Propenoic acid, 2-ethyl-2-[[(1-oxo-2- propenyl)oxy]methyl]-1,3-propanediyl ester	15625-89-5	<= 10 %	H315, H319, H317
Benzenamine, N-nitroso-N-phenyl-	86-30-6	<= 3 %	H351, H411

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

4. FIRST AID MEASURES

Inhalation:

If inhaled, remove victim to fresh air.

Skin:

In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eyes:

Immediately flush eye(s) with plenty of water.

Ingestion:

If swallowed, DO NOT induce vomiting. Get medical attention. Never give anything by mouth to an unconscious person.

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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:

When burned, the following hazardous products of combustion can occur: Carbon oxides nitrogen oxides 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. 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.

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7. HANDLING AND STORAGE

Handling

General information on handling:

Do not taste or swallow. Avoid contact with skin, eyes and clothing. Avoid breathing vapor or mist. Keep container 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.

Storage stability – Remarks:

Inhibitor levels should be maintained. The typical shelf-life for this product is 12 months.

Storage incompatibility – General:

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

Temperature tolerance – Do not store below:-32 °F (0 °C)

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, 2-methyl-, 2-ethyl-2-[[(2-methyl-1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester (3290-92-4)

US. OARS. WEELs Workplace Environmental Exposure Level Guide

Skin designation Remarks:

Can be absorbed through the skin.

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Time weighted average

SAFETY DATA SHEET

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Avoid skin or eye contact with liquids or aerosols.				
Listed				
2-Propenoic acid, 2-ethyl-2-[[(1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester (15625-89-5)				
US. OARS. WEELs Workplace Environmental Exposure Level Guide				
Can be absorbed through the skin.				
1 mg/m3 Avoid skin or eye contact with liquids or aerosols.				

Listed

 $1 ma/m^2$

Remarks:

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:

Avoid breathing 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 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. (in case of higher concentration)

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.

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Eye protection: Where eye contact may be likely, wear chemical goggles and have eye flushing equipment available.

9. PHYSICAL AND CHEMICAL PROPERTIES		
Color:	dark amber	
Physical state:	liquid	
Odor:	acrylic-like	
Odor threshold:	No data available	
Flash point	> 201 °F (94 °C) (Pensky-Martens closed cup)	
Auto-ignition temperature:	No data available	
Lower flammable limit (LFL):	No data available	
Upper flammable limit (UFL):	No data available	
pH:	~ 7	
Density:	No data available	
Specific Gravity (Relative density):	1.061 (77 °F(25 °C))	
Vapor pressure:	No data available	
Vapor density:	No data available	
Boiling point/boiling range:	No data available	
Melting point/range:	No data available	
Freezing point:	No data available	
Evaporation rate:	No data available	
Solubility in water:	negligible	
Viscosity, dynamic:	45 mPa.s 77 °F (25 °C) (Method: Brookfield)	
Oil/water partition coefficient:	No data available	

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Thermal decomposition: No data available

Flammability:

See GHS Classification in Section 2

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

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 Nitrogen oxides (NOx) Methacrylates Acrylates Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

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

Oral:

Acute toxicity estimate > 5,000 mg/kg.

Data for 2-Propenoic acid, 2-methyl-, 2-ethyl-2-[[(2-methyl-1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester (3290-92-4)

Acute toxicity

Dermal: Practically nontoxic. (Rabbit) LD50 > 5.000 mg/kg.

Inhalation: No deaths occurred. (Rat) 8 h Exposure time (saturated vapor)

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Skin Irritation:

Causes mild skin irritation. (Rabbit) (4 - 6 h)

Causes skin irritation. (Rabbit) (5 d) (Repeated skin exposure)

Eye Irritation:

Causes mild eye irritation. (Rabbit) 0.0 - 8.1 / 110.

Skin Sensitization:

Not a sensitizer. Guinea pig maximization test. Both positive and negative responses have been reported.

Repeated dose toxicity

Repeated dermal administration to mouse / affected organ(s): skin, site of contact / signs: structural organ changes, fibrosis

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

Carcinogenicity

Chronic dermal administration to mouse / No increase in tumor incidence was reported. (According to limited available data)

Genotoxicity

Assessment in Vitro:

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

Both positive and negative responses for genetic changes were observed in laboratory tests using: animal cells, human cells

Genotoxicity

Assessment in Vivo:

No genetic changes were observed in laboratory tests using: rats, mice

Reproductive effects

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

Other information

Possible cross sensitization with other acrylates and methacrylates.

Data for 2-Propenoic acid, 2-ethyl-2-[[(1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester (15625-89-5)

Acute toxicity

Dermal: Practically nontoxic. (Rabbit) LD50 = 5,170 mg/kg.

Practically nontoxic. (Rat) LD50 > 2,000 mg/kg.

Inhalation: No deaths occurred. (Rat) 6 h LC0 > 0.55 mg/l. (vapor)

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Skin Irritation:

Causes mild skin irritation. (Rabbit) Irritation Index: 2.2 - 3.8 / 8. (4 h)

Causes skin irritation. (Rabbit) (6 h) (Repeated skin exposure)

Eye Irritation:

Causes serious eye irritation. (Rabbit) Irritation Index: 44/110.

Skin Sensitization:

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

Not a sensitizer. Mouse ear swelling assay. No skin allergy was observed

Repeated dose toxicity

Repeated dermal administration to rat, mouse, rabbit / affected organ(s): skin / signs: Local irritation / No adverse systemic effects reported.

Genotoxicity

Assessment in Vitro:

Both positive and equivocal responses have been reported in tests using: bacteria

Genetic changes were observed in laboratory tests using: animal cells

Genotoxicity

Assessment in Vivo: No genetic changes were observed in a laboratory test using: mice

Developmental toxicity

Exposure during pregnancy. Oral (Rat) / No birth defects were observed.

Human experience

Skin contact: Skin: Skin allergy was observed. Sensitization described in isolated cases. (based on reports of occupational exposure to workers)

Data for Benzenamine, N-nitroso-N-phenyl- (86-30-6)

Acute toxicity

Dermal:

Practically nontoxic (rabbit) LD50 > 7,940 mg/kg.

Eye Irritation:

Causes mild eye irritation. (rabbit)

Carcinogenicity

Chronic dietary administration to mouse / No increase in tumor incidence was reported.

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Chronic dietary administration to rat / affected organ(s): urinary bladder / Increase in tumor incidence was reported. Classified by the International Agency for Research on Cancer as: Group 3: Unclassifiable as to carcinogenicity in humans.

Suspected of causing cancer.

Genotoxicity

Assessment in Vitro:

Both positive and negative responses for genetic changes were observed in laboratory tests using: bacteria, animal cells

Genotoxicity

Assessment in Vivo:

No genetic changes were observed in laboratory tests using: rats, mice

An equivocal response has been reported in a test using: fruit flies

12. ECOLOGICAL INFORMATION

Chemical Fate and Pathway

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

Data for 2-Propenoic acid, 2-methyl-, 2-ethyl-2-[[(2-methyl-1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester (3290-92-4)

Biodegradation: Not readily biodegradable. (28 d) biodegradation 29 - 53 %

Octanol Water Partition Coefficient:

 $\log Pow = 2.7 - 4.2$

Data for 2-Propenoic acid, 2-ethyl-2-[[(1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester (15625-89-5)

Biodegradation:

Readily biodegradable. (28 d) biodegradation 86 %

Octanol Water Partition Coefficient: log Pow = 0.67

Data for Benzenamine, N-nitroso-N-phenyl- (86-30-6)

Biodegradation: Readily biodegradable. (7 d) biodegradation 98 %

Bioaccumulation:

Low potential to bioaccumulate 14 d BCF = 217 (Lepomis macrochirus (Bluegill sunfish))

Octanol Water Partition Coefficient: log Pow = 2.57 - 3.13

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Ecotoxicology

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

Data for 2-Propenoic acid, 2-methyl-, 2-ethyl-2-[[(2-methyl-1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester (3290-92-4)

Aquatic toxicity data:

Toxic. Oncorhynchus mykiss (rainbow trout) 96 h LC50 = 2 mg/l

Aquatic invertebrates:

Toxic. Daphnia magna (Water flea) 48 h EC50 = 9.22 mg/l

Algae:

Toxic. Pseudokirchneriella subcapitata (green algae) 72 h EC50 = 1.11 - 3.88 mg/l

Microorganisms:

Respiration inhibition / Activated sludge 3 h EC50 > 1,000 mg/l

Chronic toxicity to fish:

Pimephales promelas (fathead minnow) 32 d NOEC 0.138 mg/l

Data for 2-Propenoic acid, 2-ethyl-2-[[(1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester (15625-89-5)

Aquatic toxicity data:

Toxic. Leuciscus idus (Golden orfe) 96 h LL50 = 1.47 mg/l

Aquatic invertebrates:

Harmful. Daphnia magna (Water flea) 48 h EC50 = 19.9 mg/l

Algae:

Toxic. Desmodesmus subspicatus (green algae) 96 h EC50 = 4.86 mg/l

Microorganisms:

Activated sludge 30 min EC20 (Respiration inhibition) = 625 mg/l

Data for Benzenamine, N-nitroso-N-phenyl- (86-30-6)

Aquatic toxicity data:

Toxic. Lepomis macrochirus (Bluegill sunfish) 96 h LC50 = 5.8 mg/l

Aquatic invertebrates:

Toxic. Daphnia magna (Water flea) 48 h EC50 = 7.8 mg/l

Algae:

Toxic. Cell multiplication inhibition test / Raphidocelis subcapitata 72 h ErC50 > 4 mg/l

Chronic toxicity to aquatic invertebrates: Toxic. Daphnia magna (Water flea) 21 d NOEC (Reproduction inhibition) = 0.075 mg/l

Chronic toxicity to aquatic plants: Cell multiplication inhibition test / Raphidocelis subcapitata 72 h ErC10 = 2.2 mg/l

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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 Proper shipping name Technical name Class Packaging group Marine pollutant International Maritime Dangerous	: : : : Goo	3082 Environmentally hazardous substance, liquid, n.o.s. (Propylidynetrimethyl trimethacrylate) 9 III yes
UN Number	:	
Proper shipping name		ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Technical name	:	(PROPYLIDYNETRIMETHYL TRIMETHACRYLATE)
Class	:	9
Packaging group	:	
Marine pollutant	:	yes

15. REGULATORY INFORMATION

Chemical Inventory Status

Flash point

EU. EINECS	EINECS	Conforms to
US. Toxic Substances Control Act	TSCA	The components of this product are all on the TSCA Inventory.
Canadian Domestic Substances List (DSL)	DSL	All components of this product are on the Canadian DSL
China. Inventory of Existing Chemical Substances in China (IECSC)	IECSC (CN)	Conforms to
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Conforms to

> 201 °F (94 °C) Pensky-Martens closed cup

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Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Conforms to
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Conforms to
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	Does not conform
Australia Inventory of Chemical Substances (AICS)	AICS	Conforms to

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:

Acute Health Hazard, Chronic Health Hazard, Reactivity Hazard

SARA Title III – Section 313 Toxic Chemicals:

The following components are subject to reporting levels established by SARA Title III, Section 313:

Chemical Name	CAS-No.	De minimis concentration	Reportable threshold:
Benzenamine, N-nitroso-N-phenyl-	86-30-6	1.0 %	10000 lbs (Otherwise used (non- manufacturing/processing)) 25000 lbs (Manufacturing and processing)

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

Chemical Name
Benzenamine, N-nitroso-N-phenyl-

<u>CAS-No.</u> 86-30-6 Reportable quantity 100 lbs

United States – State Regulations

New Jersey Right to Know

<u>Chemical Name</u> Benzenamine, N-nitroso-N-phenyl<u>CAS-No.</u> 86-30-6

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New Jersey Right to Know – Special Health Hazard Substance(s)			
<u>Chemical Name</u> Benzenamine, N-nitroso-N-phenyl-	<u>CAS-No.</u> 86-30-6		
Pennsylvania Right to Know			
<u>Chemical Name</u> 2-Propenoic acid, 2-methyl-, 2-ethyl-2-[[(2-methyl-1-oxo-2- propenyl)oxy]methyl]-1,3-propanediyl ester	<u>CAS-No.</u> 3290-92-4		
2-Propenoic acid, 2-ethyl-2-[[(1-oxo-2- propenyl)oxy]methyl]-1,3-propanediyl ester	15625-89-5		
Benzenamine, N-nitroso-N-phenyl-	86-30-6		
Pennsylvania Right to Know – Environmentally Hazardo	us Substance(s)		
Chemical Name	CAS-No.		
Benzenamine, N-nitroso-N-phenyl-	86-30-6		
California Prop. 65 WARNING! This product contains a chemical known to the S	State of California to cause cancer.		
<u>Chemical Name</u> Benzenamine, N-nitroso-N-phenyl-	<u>CAS-No.</u> 86-30-6		
California Prop. 65 WARNING: This product contains a chemical known to the S other reproductive harm.	State of California to cause birth defects or		
<u>Chemical Name</u> Benzene, methyl-	<u>CAS-No.</u> 108-88-3		
16. OTHER INFORMATION			
Full text of H-Statements referred to under sections 2 anH315Causes skin irritation.H317May cause an allergic skin reaction.H319Causes serious eye irritation.H351Suspected of causing cancer.H411Toxic to aquatic life with long lasting effects.Latest Revision(s):Reference number:200004469Date of Revision:12/04/2015Date Printed:12/05/2015	ud 3.		

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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/medicaldevice-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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