

SAR-GEL® Blue**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: SAR-GEL® Blue
Synonyms: Mixture
Molecular formula: Proprietary Mixture
Chemical family: Mixture
Product use: Water detection in hydrocarbons

2. HAZARDS IDENTIFICATION**Emergency Overview**

Color: orange
Physical state: semi-solid
Form: paste
Odor: sweet

***Classification of the substance or mixture:**

Serious eye damage, Category 1, H318

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

SAR-GEL® Blue

GHS-Labeling

Hazard pictograms:



Signal word:

Danger

Hazard statements:

H318 : Causes serious eye damage.

Precautionary statements:

Prevention:

P280 : Wear eye protection and face protection.

Response:

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 or doctor.

Other:

Handle in accordance with good industrial hygiene and safety practice.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Poly[oxy(methyl-1,2-ethanediyl)], α-hydro-ω-hydroxy-,	25322-69-4	>= 30 - < 60 %	Not classified

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Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	>= 30 - < 60 %	Not classified
Silica, amorphous, fumed, cryst.-free	112945-52-5	>= 5 - < 10 %	Not classified
Calcium oxide (CaO)	1305-78-8	>= 5 - < 10 %	H315, H318, H335

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

4. FIRST AID MEASURES

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. Remove contaminated clothing and shoes. 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):

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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:

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
Alcohols
Aldehydes
Carboxylic acid
Ethers
Hazardous organic compounds

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.
Observe all labeled safeguards until container is cleaned, reconditioned or destroyed.
Emptied container retains product residue.

Storage**General information on storage conditions:**

Product code: FP20936-P

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Keep in a dry, cool place. Store in closed containers, in a secure area to prevent container damage and subsequent spillage.

Storage stability – Remarks:

The typical shelf-life for this product is 12 months.

Storage incompatibility – General:

Store separate from:

Strong acids

Strong alkalis

Strong oxidizing agents

phosphorous compounds

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Poly[oxy(methyl-1,2-ethanediyl)], α-hydro-ω-hydroxy-, (25322-69-4)

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

Form:	Aerosol
Time weighted average	10 mg/m3
Form:	Aerosol
Remarks:	Listed

Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy- (25322-68-3)

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

Form:	particulate
Time weighted average	10 mg/m3
Form:	particulate
Remarks:	Listed

Silica, amorphous, fumed, cryst.-free (112945-52-5)

US. OSHA Table Z-3 (29 CFR 1910.1000)

Time weighted average	20millions of particles per cubic foot of air
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US. OSHA Table Z-3 (29 CFR 1910.1000)

Time weighted average	0.8 mg/m3
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Remarks: The exposure limit is calculated from the

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equation, $80/(\%SiO_2)$, using a value of 100% SiO₂. Lower values of % SiO₂ will give higher exposure limits.

Calcium oxide (CaO) (1305-78-8)

US. ACGIH Threshold Limit Values

Time weighted average 2 mg/m³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

PEL: 5 mg/m³

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 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. Rinse immediately if skin is contaminated. Wash contaminated clothing and 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

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equipment immediately available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color:	orange
Physical state:	semi-solid
Form:	paste
Odor:	sweet
Odor threshold:	No data available.
Flash point	No data available
Auto-ignition temperature:	No data available.
Lower flammable limit (LFL):	No data available
Upper flammable limit (UFL):	No data available
pH:	2.6 - 8
Density:	No data available.
Specific Gravity (Relative density):	No data available
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:	Slightly soluble
Viscosity, dynamic:	No data available.
Oil/water partition coefficient:	No data available.
Thermal decomposition:	No data available.

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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.

Hazardous reactions:

None under normal conditions of use.

Materials to avoid:

phosphorous compounds
Strong acids
Strong alkalis
Strong oxidizing agents

Conditions / hazards to avoid:

Store away from moisture and heat to maintain the technical properties of the product.

Hazardous decomposition products:

Thermal decomposition giving flammable and toxic products :

Carbon oxides
Aldehydes
ethers
Alcohols
Nitrogen oxides (NOx)
Carboxylic acids
Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

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

Data for Poly[oxy(methyl-1,2-ethanediyl)], α -hydro- ω -hydroxy-, (25322-69-4)

Acute toxicity

Oral:

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

Dermal:

No deaths occurred. (rabbit) LD0 > 3,000 mg/kg.

Inhalation:

No deaths occurred. (rat) 1 h LC0 > 0.17 mg/l.

Skin Irritation:

Not irritating. (rabbit)

Eye Irritation:

Not irritating. (rabbit)

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Skin Sensitization:

Not a sensitizer. LLNA: Local Lymph Node Assay. (mouse) No skin allergy was observed.

Not a sensitizer. Buehler method. (guinea pig) No skin allergy was observed.

Repeated dose toxicity

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

Genotoxicity**Assessment in Vitro:**

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

Developmental toxicity

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

Reproductive effects

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

Other information

The information presented is from representative materials with this Chemical Abstract Service (CAS) Registry number. The results vary depending on the size and composition of the test substance.

Data for Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy- (25322-68-3)**Acute toxicity****Oral:**

Practically nontoxic. (rat) LD50 > 2,000 mg/kg. signs: No specific toxic effects

Dermal:

Practically nontoxic. (rabbit) LD50 > 2,000 mg/kg. signs: No specific toxic effects

Inhalation:

No deaths occurred. (rat, mouse) 6 h LC0 = 2.5 mg/l. (dust/mist)

Skin Irritation:

Not irritating. (rabbit) Draize Test

Eye Irritation:

Causes mild eye irritation. (rabbit)

Skin Sensitization:

Not a sensitizer. Repeat Insult Patch Test (HRIPT). No skin allergy was observed.

Not a sensitizer. Guinea pig maximization test. (Guinea pig) No skin allergy was observed.

Repeated dose toxicity

Subchronic Inhalation administration to rabbit / No adverse systemic effects reported.

Chronic Oral administration to rat and dog / No adverse effects reported.

SAR-GEL® Blue**Genotoxicity****Assessment in Vitro:**

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

Developmental toxicity

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

Reproductive effects

Multiple generation reproduction test. oral (rat) / No toxicity to reproduction

Human experience**Skin contact:**

Skin: rash. (subjects with dermatitis or eczema)

Skin: No skin allergy was observed. (studied using human volunteers)

Data for Silica, amorphous, fumed, cryst.-free (112945-52-5)**Acute toxicity****Oral:**

No deaths occurred. (rat) LD50 > 5,000 mg/kg.

Dermal:

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

Inhalation:

No deaths occurred. (rat) 4 h LC0 > 2.08 mg/l. (dust/mist)

Skin Irritation:

Not irritating. (rat) Irritation Index: 0-2 / 8. (4 h)

Eye Irritation:

Causes mild eye irritation. (rabbit) OECD Test Guideline 405

Repeated dose toxicity

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

Repeated inhalation administration to rat / affected organ(s): lung, lymph node / signs: inflammation / No adverse systemic effects reported. (Local effects, reversible)

Carcinogenicity

Chronic dietary administration to rat and mouse / affected organ(s): lung / No increase in tumor incidence was reported.

Classified by the International Agency for Research on Cancer as: Group 3: Unclassifiable as to carcinogenicity in humans.

Genotoxicity**Assessment in Vitro:**

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

Genotoxicity

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Assessment in Vivo:

No genetic changes were observed in a laboratory test using: rats

Developmental toxicity

Exposure during pregnancy. Oral (rat, rabbit, hamster, mouse) / No birth defects were observed.

Other information

Information given is based on data obtained from similar substances.

Human experience**Inhalation:**

Respiratory system: No increase in tumor incidence was reported. No significant impairment of lung function. (based on reports of occupational exposure to workers)

Data for Calcium oxide (CaO) (1305-78-8)**Acute toxicity****Oral:**

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

Dermal:

No deaths occurred. (rabbit) LD0 > 2,500 mg/kg.

Inhalation:

Practically nontoxic. (rat) 4 h LC50 > 6.04 mg/l. (data for a similar material)

Specific target organ toxicity - single exposure:

May cause respiratory irritation.

Skin Irritation:

Causes mild skin irritation. (rabbit)

Eye Irritation:

Causes serious eye damage. (rabbit)

Skin Sensitization:

Not a sensitizer. LLNA: Local Lymph Node Assay. (mouse) No skin allergy was observed. (data for a similar material)

Repeated dose toxicity

Repeated oral, inhalation administration to rat / No adverse systemic effects reported. (data for a similar material)

Carcinogenicity

Chronic oral administration to rat / No increase in tumor incidence was reported. (data for a similar material)

Genotoxicity**Assessment in Vitro:**

No genetic changes were observed in laboratory tests using: bacteria

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No genetic changes were observed in a laboratory test using: animal cells, human cells, (data for a similar material)

Genotoxicity**Assessment in Vivo:**

No genetic changes were observed in laboratory tests using: rats

Developmental toxicity

Exposure during pregnancy. Oral (rat and mouse) / No birth defects were observed.

Reproductive effects

Reproductive/Developmental Effects Screening Assay. oral (rat) / No toxicity to reproduction. / (data for a similar material)

Human experience**Inhalation:**

Upper respiratory tract: Discomfort, coughing, irritation, perforation of the nasal septum. (extent of injury depends on severity of exposure)

Human experience**Skin contact:**

Irritation, burning of skin. Irritant but not a sensitizer.

Human experience**Eye contact:**

Severe irritation.

12. ECOLOGICAL INFORMATION**Chemical Fate and Pathway**

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

Data for Poly[oxy(methyl-1,2-ethanediyl)], α -hydro- ω -hydroxy-, (25322-69-4)**Biodegradation:**

Readily biodegradable. (28 d) biodegradation 86.6 %

Octanol Water Partition Coefficient:

log Pow: = 0.3 - 0.9, at 73 °F (23 °C)

Additional Information:

The information presented is from representative materials with this Chemical Abstract Service (CAS) Registry number. The results vary depending on the size and composition of the test substance.

Data for Poly(oxy-1,2-ethanediyl), .alpha.-hydro.-omega.-hydroxy- (25322-68-3)**Biodegradation:**

Readily biodegradable. (28 d) biodegradation 74.9 % / OECD Test Guideline 301 D

Octanol Water Partition Coefficient:

log Pow: -0.698, at 86 °F (30 °C) pH = 6.44

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Ecotoxicology

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

Data for Poly[oxy(methyl-1,2-ethanediyl)], α -hydro- ω -hydroxy-, (25322-69-4)

The information presented is from representative materials with this Chemical Abstract Service (CAS) Registry number. The results vary depending on the size and composition of the test substance.

Aquatic toxicity data:

Practically nontoxic. Danio rerio (zebra fish) 96 h LC50 > 100 mg/l

Aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 48 h EC50 = 106 mg/l

Algae:

Practically nontoxic. Desmodesmus subspicatus (green algae) 72 h EC50 > 100 mg/l

Microorganisms:

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

Chronic toxicity to aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 21 d NOEC > 10 mg/l

Chronic toxicity to aquatic plants:

Practically nontoxic. Desmodesmus subspicatus (green algae) 72 h NOEC = 100 mg/l

Data for Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy- (25322-68-3)**Aquatic toxicity data:**

Practically nontoxic. Poecilia reticulata (guppy) 24 h LC50 > 100 mg/l

Aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 48 h EC50 > 100 mg/l

Data for Silica, amorphous, fumed, cryst.-free (112945-52-5)**Aquatic toxicity data:**

No effect up to the limit of solubility. Brachydanio rerio (zebrafish) 96 h LL50 > 10,000 mg/l (nominal concentrations reported)

Aquatic invertebrates:

No effect up to the limit of solubility. Daphnia (water flea) 24 h EL50 > 10,000 mg/l (nominal concentrations reported)

Data for Calcium oxide (CaO) (1305-78-8)**Aquatic toxicity data:**

Harmful. Oncorhynchus mykiss (rainbow trout) 96 h LC50 = 50.6 mg/l

Aquatic invertebrates:

Harmful. Daphnia magna (Water flea) 48 h EC50 = 49.1 mg/l

Algae:

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Practically nontoxic. Pseudokirchneriella subcapitata (green algae) 72 h EC50 = 184 mg/l

Chronic toxicity to aquatic plants:

Practically nontoxic. Pseudokirchneriella subcapitata (green algae) 72 h NOEC = 48 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.

14. TRANSPORT INFORMATION

US Department of Transportation (DOT): not regulated

International Maritime Dangerous Goods Code (IMDG): not regulated

15. REGULATORY INFORMATION

Chemical Inventory Status

US. Toxic Substances Control Act	TSCA	The components of this product are all on the TSCA Inventory.
Canadian Domestic Substances List (DSL)	DSL	This product contains one or several components listed in the Canadian NDSL list. All other components are on the DSL list.
China. Inventory of Existing Chemical Substances in China (IECSC)	IECSC (CN)	Does not conform
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Does not conform
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Does not conform
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Does not conform
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	Conforms to
Australia Inventory of Chemical Substances (AICS)	AICS	Does not conform

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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

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):

The components in this product are either not CERCLA regulated, regulated but present in negligible concentrations, or regulated with no assigned reportable quantity.

United States – State Regulations

New Jersey Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
Calcium oxide (CaO)	1305-78-8

New Jersey Right to Know – Special Health Hazard Substance(s)

<u>Chemical name</u>	<u>CAS-No.</u>
Calcium oxide (CaO)	1305-78-8

Pennsylvania Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
Poly[oxy(methyl-1,2-ethanediyl)], α-hydro-ω-hydroxy-,	25322-69-4

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3
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Silica, amorphous, fumed, cryst.-free	112945-52-5
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Calcium oxide (CaO)	1305-78-8
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SAR-GEL® Blue**California Prop. 65**

WARNING! This product contains a chemical known to the State of California to cause cancer.

Chemical name
Quartz (SiO₂)

CAS-No.
14808-60-7

16. OTHER INFORMATION**Full text of H-Statements referred to under sections 2 and 3.**

H315 Causes skin irritation.
H318 Causes serious eye damage.
H335 May cause respiratory irritation.

Latest Revision(s):

Reference number: 200018000
Date of Revision: 10/28/2019
Date Printed: 10/28/2019

SAR-GEL® is a registered trademark of Arkema Inc.

The statements, technical information and recommendations contained herein are believed to be accurate as of the date hereof. Since the conditions and methods of use of the product and of the information referred to herein are beyond our control, ARKEMA expressly disclaims any and all liability as to any results obtained or arising from any use of the product or reliance on such information; **NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE GOODS DESCRIBED OR THE INFORMATION PROVIDED HEREIN.** The information provided herein relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. The user should thoroughly test any application before commercialization. Nothing contained herein constitutes a license to practice under any patent and it should not be construed as an inducement to infringe any patent and the user is advised to take appropriate steps to be sure that any proposed use of the product will not result in patent infringement. See SDS for Health & Safety Considerations.

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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