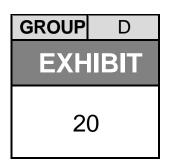


NATIONAL TRANSPORTATION SAFETY BOARD Investigative Hearing

Norfolk Southern Railway general merchandise freight train 32N derailment with subsequent hazardous material release and fires, in East Palestine, Ohio, on February 3, 2023



Agency / Organization

Arkema, Inc.

Title

Butyl Acrylate Safety Data Sheet

Docket ID: DCA23HR001



BUTYL ACRYLATE

1. PRODUCT AND COMPANY IDENTIFICATION

NO NUM:DIV IDENTIFIER MAINTAINED FOR THIS SPECIFICATION!

Company

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

Methacrylics

Customer Service Telephone Number: 1-800-338-1015

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

Emergency Information

CHEMTREC: (800) 424-9300 **Transportation:** (24 hrs., 7 days a week)

Medical:

Rocky Mountain Poison Center: (866) 767-5089

(24 hrs., 7 days a week)

Product Information

Product name: **BUTYL ACRYLATE** Synonyms: **BUTYL ACRYLATE**

Molecular formula: C7H12O2 Chemical family: acrylates Molecular weight: 128 g/mol Product use: Intermediate

2. HAZARDS IDENTIFICATION

Emergency Overview

Color: colourless Physical state: liquid Odor: like fruit

*Classification of the substance or mixture:

Flammable liquid., Category 3, H226 Inhalation: Acute toxicity, Category 4, H332 Skin irritation, Category 2, H315 Eye irritation, Category 2A, H319 Skin sensitisation, Category 1, H317 Specific target organ toxicity - single exposure, Category 3, H335

Chronic aquatic toxicity, Category 3, H412

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

Page: 1 / 15 Product code: 154111 Version 3.0 Issued on: 01/21/2017





GHS-Labelling

Hazard pictograms:





Signal word: Warning

Hazard statements:

H226: Flammable liquid and vapour.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

H335: May cause respiratory irritation.

H412 : Harmful to aquatic life with long lasting effects.



BUTYL ACRYLATE

Precautionary statements:

Prevention:

P210: Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P233: Keep container tightly closed.

P240: Ground/bond container and receiving equipment.

P241: Use explosion-proof electrical/ ventilating/ lighting/ equipment.

P242: Use only non-sparking tools.

P243: Take precautionary measures against static discharge.

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

P264: Wash skin thoroughly after handling.

P271: Use only outdoors or in a well-ventilated area.

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

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

P273: Avoid release to the environment.

Response:

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.

P312: Call a POISON CENTER/doctor if you feel unwell.

P321: Specific treatment (see supplemental first aid instructions on this label).

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

P337 + P313 : If eye irritation persists: Get medical advice/ attention.

P362: Take off contaminated clothing and wash before reuse.

P370 + P378: In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

Storage:

P403 + P233 : Store in a well-ventilated place. Keep container tightly closed.

P403 + P235 : Store in a well-ventilated place. Keep cool.

P405: Store locked up.

Disposal:

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

Supplemental information:

Potential Health Effects:

If swallowed, may cause gastrointestinal irritation including nausea and vomiting. Vapor causes irritation to the respiratory tract and the eyes. Possible cross sensitization with other acrylates and methacrylates.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
2-Propenoic acid, butyl ester	141-32-2	>= 99 %	H226, H332, H315, H319, H317, H335, H412

^{**}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 to fresh air and keep at rest in a position comfortable for breathing. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Skin:

In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. 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.

Ingestion:

If swallowed, DO NOT induce vomiting. Get medical attention. 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) 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), Dry chemical, Foam

Extinguishing media (unsuitable):

Water may be ineffective., Do not use a solid water stream as it may scatter and spread fire.

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BUTYL ACRYLATE

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.

Explosion hazard

Cool closed containers exposed to fire with water spray.

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

After a fire, wait until the material has cooled to room temperature before initiating clean-up activities.

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

Fire fighting equipment should be thoroughly decontaminated after use.

Vapors are heavier than air and may travel along the ground or be moved by ventilation and ignited by heat, pilot lights, and other flames and ignition sources at locations distant from material handling point.

Fire and explosion hazards:

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

Carbon oxides

Hazardous organic compounds

A large amount of heat can be generated when monomers are exposed to a fire.

Heated sealed containers can explode.

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. Eliminate all ignition sources. Avoid generation of vapors. Contain and collect spillage with noncombustible absorbent material such as sodium bicarbonate, sodium carbonate, calcium carbonate, clean sand or non-acidic clay and then wet down (dampen) the mixture with water. Sweep or scoop up using non-sparking tools and place into suitable properly labeled containers for prompt disposal. The sweepings should be wetted down further with water. 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:

Avoid breathing vapor or mist.

Avoid contact with skin, eyes and clothing.

Keep away from heat, sparks and flames.

No smoking.

Keep container closed.

Use only with adequate ventilation.

Vapors are heavier than air and may travel along the ground or be moved by ventilation and ignited by heat, pilot lights, and other flames and ignition sources at locations distant from material handling point.

Wash thoroughly after handling.

Check that all equipment is properly grounded and installed to satisfy electrical classification requirements.

Container hazardous when empty.

Follow label warnings even after container is emptied.

RESIDUAL VAPORS MAY EXPLODE ON IGNITION.

DO NOT CUT, DRILL, GRIND, OR WELD ON OR NEAR THIS CONTAINER.

Improper disposal or reuse of this container may be dangerous and/or illegal.

Emptied container retains vapor and product residue.

Storage

General information on storage conditions:

Keep in a dry, cool place. Store in tightly closed container. Keep away from direct sunlight. Keep container closed when not in use. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Store in well ventilated area away from heat and sources of ignition such as flame, sparks and static electricity. An air space is required above the liquid in all containers; avoid storage under an oxygen-free atmosphere. Ensure that all storage and handling equipment is properly grounded and installed to satisfy electrical classification requirements. Static electricity may accumulate when transferring material. All metal and groundable storage containers, including but not limited to drums, cylinders, Returnable Intermodal Bulk Containers (RIBCs) and Class C Flexible Intermodal Bulk Containers (FIBCs) must be bonded and grounded during filling and emptying operations. Observe all federal, state and local regulations and National Fire Protection Association (NFPA) Codes which pertain to the specific local conditions of storage and use, including OSHA 29 CFR 1910.106 and NFPA 30, 70, 77, and 497.

Storage stability - Remarks:

The typical shelf-life for this product is 12 months. The stability of this product should be checked periodically; typically every 90 days for bulk containers. Materials recommended for packaging include: stainless steel, aluminum, glass, HDPE, PP or PTFE. Recommended oxygen level is 5 to 8% by volume. Recommended inhibitor level is 10 to 20 ppm. Uninhibited monomer vapors can polymerize and plug relief devices.

Storage incompatibility - General:

Store away from sources of heat and light. Store separate from:

Free radical generators

Peroxides

Strong oxidizing agents

Amines

Rust

Anhydrides

Aldehydes

Azides

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Strong bases Mercaptans Halides Ethers Mineral acids

Temperature tolerance - Do not store above:

86 °F (30 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

2-Propenoic acid, butyl ester (141-32-2)

US. ACGIH Threshold Limit Values

Time weighted average 2 ppm

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.

Consult ACGIH ventilation manual or NFPA Standard 91 for design of exhaust systems.

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.

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. 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.

When handling this material, gloves of the following type(s) should be worn: butyl-rubber

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Eye protection:

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: colourless

Physical state: liquid

Odor: like fruit

Odor threshold: 0.3 ppb

Flash point 102 °F (39 °C) (closed cup)

Auto-ignition 559 °F (293 °C) (Method: Literature)

temperature:

Lower flammable limit

(LFL):

1.5 %(V) (Method: Literature)

Upper flammable limit

(UFL):

9.9 %(V) (Method: Literature)

pH: not determined

Density: not determined

Specific Gravity (Relative

density):

0.898 (68 °F(20 °C))

Vapor pressure: 0.40 mmHg (68 °F (20 °C))

Vapor density: 4.4 kg/m3 (Method: Literature)

Boiling point/boiling

range:

297 °F (147 °C)

Melting point/range: not determined

Freezing point: -83 °F (-64 °C)

Evaporation rate: No data available

Solubility in water: 2 g/l 77 °F (25 °C)

Viscosity, dynamic: 0.9 mPa.s 68 °F (20 °C)

Molecular weight: 128 g/mol

Oil/water partition = 2.38

ARKEMA

SAFETY DATA SHEET

BUTYL ACRYLATE

coefficient:

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. See HANDLING AND STORAGE section of this SDS for specified conditions.

Hazardous reactions:

Hazardous polymerisation may occur.

Avoid freezing.

After freezing and thawing, hazardous polymerization can occur if thawed incorrectly.

Materials to avoid:

Free radical generators, Peroxides, Strong oxidizing agents

Amines

Rust

Anhydrides

Aldehydes

Strong bases.

Mercaptans

Halides

Azides

Ethers Mineral acids

Conditions / hazards to avoid:

An uncontrolled polymerization may produce a rapid release of energy with the potential for an explosion of unvented closed containers or inadequately vented containers. This material polymerizes exothermically in the presence of heat, contamination, oxygen free atmosphere, free radicals, peroxides and inhibitor depletion liberating heat.

Hazardous decomposition products:

Thermal decomposition giving flammable and toxic products:

Carbon oxides

Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

Data on this material and/or a similar material are summarized below.

Data for BUTYL ACRYLATE

Acute toxicity

Oral:

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May be harmful if swallowed. (rat) LD50 = 3,143 - 9,050 mg/kg.

Dermal:

May be harmful in contact with skin. (rabbit) LD50 > 2,000 mg/kg.

Inhalation:

Harmful if inhaled. (rat) 4 h LC50 = 10.3 - 14.3 mg/l. (vapor)

Harmful if inhaled. (rat) 1 h LC50 = 23.04 - 33.3 mg/l. (vapor)

Skin Irritation:

Causes skin irritation. (rabbit) Irritation Index: 6.8/8.0. (15 min) (occluded exposure)

Causes skin irritation. (rabbit) Irritation Index: 6.5 / 8.0. (4 h)

Eye Irritation:

Causes serious eye irritation. (rabbit)

Skin Sensitization:

May cause allergic skin reaction. Guinea pig maximization test. Skin allergy was observed.

May cause allergic skin reaction. LLNA: Local Lymph Node Assay. (mouse) Produced an allergic reaction.

Repeated dose toxicity

Subchronic drinking water administration to rat / signs: changes in food or water consumption, decreased growth rate

Subchronic oral administration to rat / affected organ(s): liver / signs: increased organ weight

Subchronic inhalation administration to rat / affected organ(s): respiratory tract, eye / Local irritation

Carcinogenicity

Chronic inhalation administration to rat / No increase in tumor incidence was reported.

Chronic dermal administration to mouse / 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

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

Assessment in Vivo:

No genetic changes were observed in laboratory tests using: hamster, rat

Developmental toxicity

Exposure during pregnancy. Inhalation (Rat) / No birth defects were observed. (levels produced toxic effects in the mothers and offspring)

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BUTYL ACRYLATE

Exposure during pregnancy. Oral (Mouse) / Birth defects were observed. (levels produced toxic effects in the mothers and offspring)

Reproductive effects

Repeated exposure by inhalation (rat) / Did not cause damage to the reproductive organs.

Other information

Possible cross sensitization with other acrylates and methacrylates.

Human experience

Skin contact:

Skin allergy was observed.

12. ECOLOGICAL INFORMATION

Chemical Fate and Pathway

Data on this material and/or a similar material are summarized below.

Data for BUTYL ACRYLATE

Stability in water:

Half-life = 4 h (77 °F (25 °C) @pH 11 (Hydrolyses slowly.)

Half-life > 1,100 d (77 °F (25 °C) @pH 7 (Hydrolyses slowly.)

Half-life > 1,000 d (77 °F (25 °C) @pH 3 (Hydrolyses slowly.)

Biodegradation:

Readily biodegradable. (28 d) biodegradation > 80 %

Biological Oxygen Demand:

14 d BOD = 61% ThOD 28 d BOD = 57% ThOD

BOD/COD Ratio:

BOD/COD = 60 % (BOD5)

Bioaccumulation:

Slight potential to bioaccumulate.

Octanol Water Partition Coefficient:

log Pow = 2.38

Ecotoxicology

Data on this material and/or a similar material are summarized below.

Data for BUTYL ACRYLATE



BUTYL ACRYLATE

Aquatic toxicity data:

Toxic. Cyprinodon variegatus (sheepshead minnow) 96 h LC50 = 2.1 mg/l Toxic. Oncorhynchus mykiss (rainbow trout) 96 h LC50 = 5.2 mg/l

Aquatic invertebrates:

Toxic. Daphnia magna (Water flea) 48 h EC50 = 8.2 mg/l

Algae:

Toxic. Pseudokirchneriella subcapitata (green algae) 96 h EC50 = 2.65 mg/l

Toxic. Selenastrum capricornutum 72 h EC50 = 5.9 mg/l

Microorganisms:

Activated sludge 3 d EC0 (Respiration inhibition) > 150 mg/l

Chronic toxicity to aquatic invertebrates:

Daphnia magna (Water flea) 21 d NOEC (reproduction) = 0.14 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 : 2348

Proper shipping name : Butyl acrylates, stabilized

Class : 3
Packaging group : III
Marine pollutant : no

International Maritime Dangerous Goods Code (IMDG)

UN Number : 2348

Proper shipping name : BUTYL ACRYLATES, STABILIZED

Class : 3
Packaging group : III
Marine pollutant : no

Flash point : 102 °F (39 °C) closed cup

15. REGULATORY INFORMATION

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Chemical Inventory Status

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 E

Substances Inventory

ENCS (JP) Conforms to

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 PICCS (PH) Conforms to

Substances (PICCS)

Australia Inventory of Chemical Substances (AICS) AICS Conforms to

United States - Federal Regulations

SARA Title III - Section 302 Extremely Hazardous Chemicals:

Chemical name	CAS-No.	SARA	SARA Threshold
		Reportable	Planning Quantity
		Quantities	
1.4-Renzenedial	123_31_0	100 lbe	500 lbs

1,4-Benzenediol 123-31-9 100 lbs 500 lbs 10000 lbs

SARA Title III - Section 311/312 Hazard Categories:

Acute Health Hazard, Fire 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 nameCAS-No.De minimis concentrationReportable threshold:2-Propenoic acid, butyl ester141-32-21.0 %10000 lbs (Otherwise used (non-

manufacturing/processing)) 25000 lbs (Manufacturing and processing)

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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>
2-Propenoic acid, butyl ester

<u>CAS-No.</u>
141-32-2

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

Chemical nameCAS-No.2-Propenoic acid, butyl ester141-32-2

Pennsylvania Right to Know

Chemical nameCAS-No.2-Propenoic acid, butyl ester141-32-2

Pennsylvania Right to Know - Environmentally Hazardous Substance(s)

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

2-Propenoic acid, butyl ester 141-32-2

California Prop. 65

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

Chemical name CAS-No. 2-Propenoic acid, ethyl ester 140-88-5

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.

H226 Flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

Miscellaneous:

Other information: Refer to National Fire Protection Association (NFPA) Codes 30, 70,

77, and 497 and OSHA 29 CFR 1910.106, for safe handling.

Latest Revision(s):

Reference number: 200000034

Date of Revision: 01/21/2017

Date Printed: 01/22/2017

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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