

LUPEROX® 101PP20

1. PRODUCT AND COMPANY IDENTIFICATION**Company**

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

Functional Additives

Customer Service Telephone Number: (800) 331-7654
(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: LUPEROX® 101PP20
Synonyms: Dialkyl peroxide
Molecular formula: Complex Mixture
Chemical family: Organic peroxide - dialkyl peroxides
Product use: initiator/catalyst

SECTION 2: HAZARDS IDENTIFICATION**Emergency Overview**

Color: white
Physical state: solid
Form: powder
Odor: menthol

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

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Organic peroxides, Type E, H242
Skin irritation, Category 2, H315

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

GHS-Labeling

Hazard pictograms:



Signal word:

Warning**Hazard statements:**

H242 : Heating may cause a fire.
H315 : Causes skin irritation.

Supplemental Hazard Statements:

Organic peroxide.
Hazardous decomposition may occur.
May form combustible dust concentrations in air.

Precautionary statements:**Prevention:**

P210 : Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P220 : Keep/Store away from clothing/ combustible materials.
P234 : Keep only in original container.
P264 : Wash skin thoroughly after handling.
P280 : Wear protective gloves or eye protection or face protection.

Response:

P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.
P332 + P313 : If skin irritation occurs: Get medical advice/ attention.
P362 : Take off contaminated clothing and wash before reuse.

Storage:

P410 : Protect from sunlight.
P411 + P235 : Maximum storage temperature is specified on label and in section 7 of SDS. Keep cool.
P420 : Store away from other materials.

Disposal:

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

Supplemental information:

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Potential Health Effects:

Mechanical irritation effects from dust exposure are possible at ambient temperature.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS-No.	Wt/Wt	GHS Classification**
1-Propene, homopolymer	9003-07-0	>= 62 - <= 64 %	Not classified
Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl)	78-63-7	>= 19 - <= 21 %	H227, H242, H315
Silica gel, pptd., cryst.-free	112926-00-8	>= 10 - <= 30 %	Not classified

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

SECTION 4: FIRST AID MEASURES**4.1. Description of necessary first-aid measures:****Inhalation:**

If inhaled, remove victim to fresh air.

Skin:

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

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

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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 any immediate medical attention and special treatment needed:

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

SECTION 5: FIREFIGHTING MEASURES

Extinguishing media (suitable):

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

Extinguishing media (unsuitable):

High volume water jet

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:

Do not use a solid stream of water.

A solid stream of water can cause a dust explosion.

Fight fire with large amounts of water from a safe distance.

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.

Fire fighting equipment should be thoroughly decontaminated after use.

Fire and explosion hazards:

Dust clouds generated during handling and/or storage can form explosive mixtures with air. Dust explosion characteristics vary with the particle size, particle shape, moisture content, contaminants, and other variables.

Note: Check that all equipment is properly grounded and installed to satisfy electrical classification requirements. As with any dry material, pouring this material or allowing it to free-fall or to be conveyed through chutes or pipes can accumulate and generate electrostatic sparks, potentially causing ignition of the material itself, or of any flammable materials which may come into contact with the material or its container.

Contact with incompatible materials or exposure to temperatures exceeding the SADT may result in a self accelerating decomposition reaction with release of flammable vapors which may autoignite.

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

Carbon oxides

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. Eliminate all ignition sources. Avoid dust formation and dispersal of dust in the air. Wet down (dampen) the spilled material 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. Implement workplace practices such that dusts are not allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

SECTION 7: HANDLING AND STORAGE**Handling****General information on handling:**

Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.

Avoid breathing dust.

Keep away from heat, sparks and flames.

No smoking.

Avoid contact with skin, eyes and clothing.

Wash thoroughly after handling.

Prevent product contamination.

Keep container tightly closed and away from combustible materials.

Keep only in the original container.

Use only with adequate ventilation.

Avoid creating dust in handling, transfer or clean up.

Prevent dust accumulation.

Implement routine housekeeping practices to ensure that dusts do not accumulate on surfaces.

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

Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations.

Container hazardous when empty.

Follow label warnings even after container is emptied.

RESIDUAL DUSTS 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 product residue.

Storage**General information on storage conditions:**

Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Segregated or

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detached storage is preferred. Store in well ventilated area away from heat and sources of ignition such as flame, sparks and static electricity. Ensure that all storage and handling equipment is properly grounded and installed to satisfy electrical classification requirements. Store out of direct sunlight in a cool well-ventilated place. Store in original container. Store away from combustibles and materials to avoid. Refer also to National Fire Protection Association (NFPA) Code 400, Hazardous Materials Code. 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 NFPA 654.

Storage stability – Remarks:

Follow the recommended storage temperatures provided in this Section in order to maintain stability and oxygen content.

Storage incompatibility – General:

Store away from excessive heat, sources of ignition, and reactive materials.

Store separate from:

Strong acids

Strong oxidizing agents

Reducing agents

Friedel - Crafts reaction catalyst

Accelerators

Brass

Copper

Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Temperature tolerance – Do not store above:

100 °F (38 °C)

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Silica gel, pptd., cryst.-free (112926-00-8)

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

Time weighted average 20millions of particles per cubic foot of air

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

Time weighted average 0.8 mg/m3

Remarks: The exposure limit is calculated from the equation, 80/(%SiO2), using a value of 100%

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SiO2. Lower values of % SiO2 will give higher exposure limits.

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.

Check that all dust control equipment such as local exhaust ventilation, material transport systems, and air-material separation devices involved in handling this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Isolation devices may be appropriate to prevent propagation from one unit to another. Ensure that dust-handling systems are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Consult ACGIH ventilation manual, NFPA Standard 91 and NFPA Standard 654 for design of exhaust system and safe handling.

Respiratory protection:

Avoid breathing dust. 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. Wash thoroughly after handling.

Eye protection:

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Color:	white
Physical state:	solid
Form:	powder

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Odor:	menthol
Odor threshold:	No data available
Flash point	The flashpoint of this product is greater than the Self Acceleration Decomposition Temperature (SADT).
Auto-ignition temperature:	No data available.
Lower flammable limit (LFL):	No data available
Upper flammable limit (UFL):	No data available
pH:	Not applicable
Density:	No data available
Specific Gravity (Relative density):	No data available
Boiling point/boiling range:	Decomposes before boiling. Rate of decomposition increases with rising temperature.
Melting point/range:	> 320 °F (> 160 °C)
Freezing point:	Not applicable
Evaporation rate:	No data available
Solubility in water:	insoluble
Viscosity, dynamic:	No data available
Oil/water partition coefficient:	No data available.
Self-Accelerating Decomposition Temperature (SADT):	estimated 180 °F (82 °C) 100 pound container
Thermal decomposition:	No data available
Active oxygen content:	2.2 %
Flammability:	See GHS Classification in Section 2 if applicable

SECTION 10: STABILITY AND REACTIVITY

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Stability:

This material is chemically unstable and should only be handled under specified conditions. See HANDLING AND STORAGE section of this MSDS for specified conditions.

Hazardous reactions:

Hazardous polymerization does not occur.

Materials to avoid:

Strong acids
Strong oxidizing agents
Reducing agents
Accelerators
Friedel - Crafts reaction catalyst
Brass
Copper
Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Conditions / hazards to avoid:

See HANDLING AND STORAGE section of this MSDS for specified conditions. SADT - Self Accelerating Decomposition Temperature. Lowest temperature at which the tested package size will undergo a self-accelerating decomposition reaction. This reaction will generate flammable vapors which may autoignite. The length of time to generate a decomposition reaction, after the SADT has been reached or exceeded, is dependent upon how much the SADT has been exceeded and the length of time needed for the reaction exotherm (heat spike from increasing decomposition rate) to initiate a rapid decomposition reaction. Typically, SADT is inversely proportional to package size. Larger packages will have a lower SADT due to smaller ratio to heat transfer area to volume of product.

Hazardous decomposition products:

Temperatures at or above SADT can result in the release of hazardous decomposition products which are flammable and may autoignite.

Thermal decomposition giving flammable and toxic products :

Carbon oxides
Hazardous organic compounds

SECTION 11: TOXICOLOGICAL INFORMATION

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

Data for LUPEROX® 101PP20**Acute toxicity****Dermal:**

Acute toxicity estimate > 5,000 mg/kg.

Data for 1-Propene, homopolymer (9003-07-0)**Acute toxicity**

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Oral:

Practically nontoxic. (rat) LD50 > 8,000 mg/kg.

Skin Sensitization:

Not a sensitizer. Repeated skin exposure. (guinea pig) No skin allergy was observed

Repeated dose toxicity

Chronic dietary administration to rat, mouse, dog / No adverse effects reported. (Solvent extracts were tested.)

Subchronic inhalation administration to rat / affected organ(s): lung / signs: irritation / (fiber was tested)

Intratracheal administration to rat / affected organ(s): lung / signs: fibrosis

Carcinogenicity

Chronic subcutaneous implant administration to rat / signs: tumors at the site of application / Increased incidence of tumors was reported.

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

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.

Human experience**Skin contact:**

Skin: Non-irritating.

No skin allergy was observed.

Data for Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl) (78-63-7)**Acute toxicity****Oral:**

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

Dermal:

May be harmful in contact with skin. (rabbit) LD50 = 4,100 mg/kg.

Skin Irritation:

Causes skin irritation. (rabbit) (4 h)

Eye Irritation:

Causes mild eye irritation. (rabbit)

Skin Sensitization:

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

Repeated dose toxicity

Subchronic oral administration to rat / affected organ(s): kidney / signs: hyaline droplet nephropathy

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Repeated oral administration to rat / affected organ(s): liver, kidney / signs: changes in organ weights, changes in organ structure or function, hyaline droplet nephropathy

Genotoxicity**Assessment in Vitro:**

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

Data for Silica gel, pptd., cryst.-free (112926-00-8)**Acute toxicity****Oral:**

Practically nontoxic. (rat) LD0 > 5,000 mg/kg.

Dermal:

Practically nontoxic. (rabbit) LD0 > 5,000 mg/kg.

Inhalation:

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

Skin Irritation:

Practically non-irritating. (rabbit) (4 h)

Eye Irritation:

Causes mild eye irritation. (rabbit)

Skin Sensitization:

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

Repeated dose toxicity

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

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

Carcinogenicity

Chronic dietary administration to rat and 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

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Assessment in Vitro:

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

Genotoxicity**Assessment in Vivo:**

No genetic changes were observed in laboratory tests using: rats

Developmental toxicity

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

Reproductive effects

Two-generation study. Oral (rat) / No toxicity to reproduction.

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)

SECTION 12: ECOLOGICAL INFORMATION**Chemical Fate and Pathway**

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

Data for Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl) (78-63-7)**Stability in water:**

Half-life 2.7 h (@pH 4)

Half-life 2.7 h (@pH 7)

Half-life 2.8 h (@pH 9)

Biodegradation:

Not readily biodegradable. (60 d) biodegradation 0 %

Bioaccumulation:

512 - 539 (Fish)

Octanol Water Partition Coefficient:

log Pow: = 7.34, at 68 °F (20 °C)

Ecotoxicology

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

Data for Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl) (78-63-7)**Aquatic toxicity data:**

No effect up to the limit of solubility. Oryzias latipes (Orange-red killifish) 96 h

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Algae:

No effect up to the limit of solubility. Pseudokirchneriella subcapitata 72 h

Microorganisms:

Activated sludge 3 h NOEC (Respiration inhibition) > 1,000 mg/l

Chronic toxicity to aquatic invertebrates:

No effect up to the limit of solubility. Daphnia magna (Water flea) 21 d NOEC > 0.0065 mg/l

Chronic toxicity to aquatic plants:

No effect up to the limit of solubility. Pseudokirchneriella subcapitata 72 h NOEC > 0.236 mg/l

Data for Silica gel, pptd., cryst.-free (112926-00-8)

Aquatic toxicity data:

No effect up to the limit of solubility. Brachydanio rerio (zebrafish) 96 h LC0 > 10,000 mg/l (nominal concentrations reported)

Aquatic invertebrates:

No effect up to the limit of solubility. Daphnia (water flea) 48 h EC50 > 5,000 mg/l (nominal concentrations reported)

Algae:

No effect up to the limit of solubility. Desmodesmus subspicatus (green algae) 72 h EC50 > 173 mg/l (nominal concentrations reported)

Chronic toxicity to aquatic plants:

No effect up to the limit of solubility. Desmodesmus subspicatus (green algae) 72 h NOEC = 173 mg/l (Nominal concentration)

SECTION 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.

SECTION 14: TRANSPORT INFORMATION

US Department of Transportation (DOT)

UN Number : 3108
Proper shipping name : Organic peroxide type E, solid
Technical name : (2,5-Dimethyl-2,5-di(tert-butylperoxy) hexane, <=77%)
Class : 5.2
Marine pollutant : no

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International Maritime Dangerous Goods Code (IMDG)

UN Number	:	3108
Proper shipping name	:	ORGANIC PEROXIDE TYPE E, SOLID
Technical name	:	(2,5-DIMETHYL-2,5-DI(TERT-BUTYLPEROXY) HEXANE, <=77%)
Class	:	5.2
Marine pollutant	:	no

SECTION 15: REGULATORY INFORMATION

Chemical Inventory Status

US. Toxic Substances Control Act	TSCA	The components of this product are all on the Active 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)	All components of this product are listed or exempted
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Not all components of this product are listed or exempted
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	All components of this product are listed or exempted
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	All components of this product are listed or exempted
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	All components of this product are listed or exempted
Australian Inventory of Industrial Chemicals	AU AIICL	All components of this product are listed or exempted
Taiwan Chemical Substance Inventory (TCSI)	TCSI	All components of this product are listed or exempted

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:

Organic peroxides
Skin corrosion or irritation

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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

California Prop. 65

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

Chemical name

Nickel

CAS-No.

7440-02-0

SECTION 16: OTHER INFORMATION

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

H227 Combustible liquid.
H242 Heating may cause a fire.
H315 Causes skin irritation.

Miscellaneous:

Other information: Refer to National Fire Protection Association (NFPA) Code 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Latest Revision(s):

Reference number: 200014305
Date of Revision: 09/26/2023
Date Printed: 09/27/2023

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responsible to test the suitability of any product in advance for any intended use or application and before commercialization. Nothing herein shall be construed as a license for the use of any product in a manner that might infringe any patent and it should not be construed as an inducement to infringe any patent. Please carefully review the Safety Data Sheet for the product.

The Company adheres to a strict policy that applies to the use of any of its products in medical device applications. This policy can be found at <https://www.arkema.com/global/en/social-responsibility/innovation-and-sustainable-solutions/responsible-product-management/medical-device-policy/> which is incorporated herein by reference and made a part hereof. Except as expressly authorized, the Company (i) has designated specific medical grade compositions for products used in medical device applications and Company products not so designated are not authorized for use in medical device applications and (ii) strictly prohibits the use of any of its 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 Company does not design, manufacture and/or directly sell any medical devices. The Company does not co-design, or offer assistance to any purchaser of its products, in their design, manufacture and/or sale of products for medical devices. It is the sole responsibility of the manufacturer of medical devices to determine the suitability of all raw material, products and components, including any medical grade products, in order to ensure that the medical device is safe for end-use and complies with all applicable legal and regulatory requirements and to conduct all necessary tests and inspections.