



1. PRODUCT AND COMPANY IDENTIFICATION

Company

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

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: VUL-CUP® R

Synonyms: alpha,alpha-Bis(t-butylperoxy)diisopropylbenzene

Molecular formula:
Chemical family:
Organic Peroxide
Molecular weight:
Product use:
OC20 H34 O4
Organic Peroxide
338 g/mol
Initiator

2. HAZARDS IDENTIFICATION

Emergency Overview

Color: Slightly yellow

Physical state: solid

Form: semi-crystalline Odor: pungent, unpleasant

*Classification of the substance or mixture:

Organic peroxides, Type D, H242

Chronic aquatic toxicity, Category 3, H412

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

GHS-Labelling

Hazard pictograms:





VUL-CUP® R

Signal word: Danger

Hazard statements:

H242: Heating may cause a fire.

H412: Harmful to aquatic life with long lasting effects.

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. P273: Avoid release to the environment.

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

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/ container to an approved waste disposal plant.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Peroxide, [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[(1,1-dimethylethyl)	25155-25-3	>= 90 %	H242, H413
Peroxide, 1,1-dimethylethyl 1-methyl- 1-[3-(1-methylethenyl)phenyl]ethyl	96319-55-0	< 5 %	H315, H411





Benzenemethanol, 3-[1-[(1,1-dimethylethyl)dioxy]-1-methylethyl]- α , α -dimethyl-	57913-37-8	< 5 %	H315, H319
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^{**}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.

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

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:

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, 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:



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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.

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:

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.



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.

Keep away from heat, sparks and flames.

Avoid breathing dust.

No smoking.

Use only with adequate ventilation.

Prevent product contamination.

Keep container tightly closed and away from combustible materials.

Keep only in the original container.

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.

Handle in accordance with good industrial hygiene and safety practices. These practices include avoiding unnecessary exposure and removal of material from eyes, skin, and clothing.

Do not reuse container as it may retain hazardous product residue.

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. Outside or 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 separate from:

Strong acids

Strong oxidizing agents



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Reducing agents

Friedel - Crafts reaction catalyst

Accelerators

Iron

Brass

Copper

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)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Particles Not Otherwise Specified / Nuisance Dust (Proprietary)

US. ACGIH Threshold Limit Values

Form: Inhalable particles. Time weighted average 10 mg/m3

Form: Respirable particles.

Time weighted average 3 mg/m3

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

Form: Respirable fraction.

PEL: 5 mg/m3

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

Form: Total dust PEL: 15 mg/m3

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

Form: Respirable fraction.

Time weighted average 15millions of particles per cubic foot of air

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

Form: Total dust

Time weighted average 50millions of particles per cubic foot of air

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

Form: Respirable fraction.

Time weighted average 5 mg/m3



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

Form: Total dust Time weighted average 15 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.

Check that all dust control equipment such as local exhaust ventilation, material transport systems, and airmaterial 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. 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:

Minimize skin contamination by following good industrial hygiene practice. Wearing protective gloves is recommended. Wash hands and contaminated skin thoroughly after handling.

Eve protection:

Use good industrial practice to avoid eye contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: Slightly yellow

Physical state: solid





Form: semi-crystalline

Odor: pungent, unpleasant

Odor threshold: No data available

Flash point > 167.9 °F (75.5 °C) (Method: Seta Flash Method)

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):

0.93 Water=1 (liquid)

Vapor pressure: 1.600 mmHg (122 °F (50 °C))

Boiling point/boiling

range:

No data available

Melting point/range: >= 95 - 113 °F (35 - 45 °C)

Freezing point: not determined

Evaporation rate: < 1

(n-butyl acetate = 1)

Solubility in water: Negligible

Viscosity, dynamic: No data available

338 g/mol Molecular weight:

Oil/water partition

coefficient:

No data available.

Self-Accelerating Decomposition

Temperature (SADT):

158 °F (70 °C)

Thermal decomposition: No data available

Flammability: See GHS Classification in Section 2

10. STABILITY AND REACTIVITY

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Stability:

This material is chemically unstable and should only be handled under 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

11. TOXICOLOGICAL INFORMATION

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

Oral:

Acute toxicity estimate > 5,000 mg/kg.

Data for Peroxide, [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[(1,1-dimethylethyl) (25155-25-3)

Acute toxicity

Oral:

No deaths occurred. (rat) LD0 > 2,000 mg/kg. (98 %)

Dermal:

No deaths occurred. (rat) LD0 > 2,000 mg/kg. (97 %)

Skin Irritation:



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Not irritating. (rabbit) (4 h)

Eye Irritation:

Causes mild eye irritation. (rabbit)

Skin Sensitization:

Not a sensitizer. LLNA: Local Lymph Node Assay. (mouse) No skin allergy was observed (98 %)

Repeated dose toxicity

Repeated oral administration to rat / affected organ(s): kidney / signs: 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, human cells

Developmental toxicity

Exposure during pregnancy. Oral (rat) / At high dose: Malformations were observed.

Reproductive effects

Reproductive/Developmental Effects Screening Assay. Oral (rat) / Effects on fertility / (levels produced toxic effects in the mothers and offspring, smaller litter sizes, reductions in birth weight)

Human experience

Inhalation:

Respiratory tract: irritation. Dust and/or vapor are reported to cause irritation when proper industrial hygiene controls/procedures are not used.

Human experience

Eye contact:

Eyes: irritation. (based on reports of occupational exposure to workers) Dust and/or vapor are reported to cause irritation when proper industrial hygiene controls/procedures are not used.

Data for Peroxide, 1,1-dimethylethyl 1-methyl-1-[3-(1-methylethenyl)phenyl]ethyl (96319-55-0)

Acute toxicity

Oral:

May be harmful if swallowed. (rat) LD50 = 4,700 mg/kg.

Dermal:

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

Inhalation:

No deaths occurred. (rat) 4 h LC0 = 1.2 mg/l. (vapour)

Skin Irritation:

Causes mild skin irritation. (rabbit) Irritation Index: 2.9/8. (4 h)

Causes skin irritation. (rabbit) Irritation Index: 3.8/8. (24 h) (occluded exposure)

Eye Irritation:

Not irritating. (rabbit)



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Skin Sensitization:

Not a sensitizer. Guinea pig maximization test. Skin allergy was observed. (Weak response)

Repeated dose toxicity

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

Genotoxicity

Assessment in Vitro:

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

Reproductive effects

Reproductive/Developmental Effects Screening Assay. Oral (rat) / At high dose: Effects on fertility and offspring / (toxic effects also observed in the parental animals at these doses)

Other information

The information presented is from a representative material with a similar structure. The results vary depending on the size and composition of the test substance.

Data for Benzenemethanol, 3-[1-[(1,1-dimethylethyl)dioxy]-1-methylethyl]- α,α-dimethyl- (57913-37-8)

Acute toxicity

Skin Irritation:

Causes skin irritation. (similar material)

Eye Irritation:

Causes serious eye irritation. (similar material)

Other information

The information presented is from representative materials in this chemical class. The results may vary depending on the test substance.

12. ECOLOGICAL INFORMATION

Chemical Fate and Pathway

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

Biodegradation:

Not readily biodegradable. (28 d) biodegradation 0 %

Bioaccumulation:

calculated = 536

Data for Peroxide, 1,1-dimethylethyl 1-methyl-1-[3-(1-methylethenyl)phenyl]ethyl (96319-55-0)

Biodegradation:

Not readily biodegradable. (58 d) biodegradation 0 %



Octanol Water Partition Coefficient:

log Pow: = 4.4, = 77 °F (25 °C)

Mobility and Distribution in the Environment:

Log Koc = 3.3

Additional Information:

Information given is based on data obtained from similar substances.

Ecotoxicology

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

Data for Peroxide, [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[(1,1-dimethylethyl) (25155-25-3)

Aquatic toxicity data:

No effect up to the limit of solubility. Poecilia reticulata (guppy) 96 h LC50 = 750 mg/l (Nominal concentration, similar material, Water accommodated fraction was tested.)

Aquatic invertebrates:

No effect up to the limit of solubility. Daphnia magna (Water flea) 48 h EC0 > 1 mg/l (Nominal concentration, Water accommodated fraction was tested.)

Algae:

No effect up to the limit of solubility. Pseudokirchneriella subcapitata (green algae) 72 h EC0 > 1 mg/l (Nominal concentration, Water accommodated fraction was tested.)

Microorganisms:

Practically nontoxic. Respiration inhibition / Activated sludge 30 min EC0 > 1,000 mg/l (Nominal concentration, similar material, Water accommodated fraction was tested.)

Chronic toxicity to aquatic plants:

No effect up to the limit of solubility. Pseudokirchneriella subcapitata (green algae) 72 h NOEC r

Data for Peroxide, 1,1-dimethylethyl 1-methyl-1-[3-(1-methylethenyl)phenyl]ethyl (96319-55-0)

Information given is based on data obtained from similar substances.

Aquatic invertebrates:

Toxic. Daphnia magna (Water flea) 48 h EC50 = 4.3 mg/l

Algae

No effect up to the limit of solubility. Pseudokirchneriella subcapitata (green algae) 72 h ErC50 > 100 mg/l (nominal concentrations reported)

Microorganisms:

No effect up to the limit of solubility. Activated sludge 58 h NOEC (Respiration inhibition) = 100 mg/l (nominal concentrations reported)

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



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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 Organic peroxide type D, solid

Technical name (Di-(tert-butylperoxyisopropyl) benzene, >42-100%)

Class 5.2 Marine pollutant no

International Maritime Dangerous Goods Code (IMDG)

UN Number 3106

Proper shipping name ORGANIC PEROXIDE TYPE D, SOLID

(DI-(TERT-BUTYLPEROXYISOPROPYL)BENZENE, >42-100%) Technical name

Class 5.2 Marine pollutant

Japan. ISHL - Inventory of Chemical Substances

Flash point > 167.9 °F (75.5 °C)

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 All components of this product are on the

ISHL (JP)

Canadian DSL

Conforms to

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

China (IECSC)

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

Substances Inventory

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

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<u>United States - Federal Regulations</u>

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:

Fire Hazard, Reactivity 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

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

Pennsylvania Right to Know

Chemical nameCAS-No.Peroxide, [1,3(or 1,4)-phenylenebis(1-
methylethylidene)]bis[(1,1-dimethylethyl)25155-25-3

Peroxide, 1,1-dimethylethyl 1-methyl-1-[3-(1- 96319-55-0

methylethenyl)phenyl]ethyl

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive defects.

16. OTHER INFORMATION

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

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

H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.H412 Harmful to aquatic life with long lasting effects.

H413 May cause long lasting harmful effects to aquatic life.

Miscellaneous:



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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:
 200008463

 Date of Revision:
 02/28/2018

 Date Printed:
 03/01/2018

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

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