LUPEROX® 231

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® 231
Synonyms: Peroxyketal
Molecular formula: Complex mixture
Chemical family: Organic peroxide - peroxyketals
Product use: initiator/catalyst

2. HAZARDS IDENTIFICATION

Emergency Overview

Color: Clear - colourless
Physical state: liquid
Odor: slight, menthol

***Classification of the substance or mixture:**
Flammable liquid., Category 4, H227
Organic peroxides, Type B, H241
Skin sensitisation, Category 1, H317

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

GHS-Labelling

Hazard pictograms:

Signal word: **Danger**

Hazard statements:

H227 : Combustible liquid.
H241 : Heating may cause a fire or explosion.
H317 : May cause an allergic skin reaction.

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.
P261 : Avoid breathing gas/mist/vapours/spray.
P272 : Contaminated work clothing should not be allowed out of the workplace.
P280 : Wear protective gloves/ eye protection/ face protection.

Response:
P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 : If skin irritation or rash occurs: Get medical advice/ attention.
P363 : Wash contaminated clothing before reuse.
P370 + P378 : In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

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.

Supplemental information:

Potential Health Effects:
Due to the presence of the solvent : Prolonged or repeated skin contact may cause defatting resulting in drying, redness and rash. Vapor: May cause eye, skin and respiratory tract irritation. (severity of effects depends on extent of exposure)

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl)	6731-36-8	>= 92 %	H241
Cyclohexanone, 3,3,5-trimethyl-	873-94-9	<= 8 %	H335, H332, H227
Hydroperoxide, 1,1-dimethylethyl	75-91-2	< 0.2 %	H242, H226, H302, H311, H330, H314, H318, H317, H341, H411

**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 soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eyes:
Immediately flush eye(s) with plenty of water.

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

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), Foam, Dry chemical

Extinguishing media (unsuitable):
Water may be ineffective., Do not use a solid water stream as it may scatter and spread fire.

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 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:
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.
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 generation of vapors. Contain and collect spillage with non-combustible 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. DO NOT USE peat moss. 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.

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 prolonged or repeated contact with skin.
Keep away from heat, sparks and flames.
No smoking.
Use only with adequate ventilation.
Wash thoroughly after handling.
Prevent product contamination.
Keep container tightly closed and away from combustible materials.
Keep only in the original container.
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.
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 vapor and product residue.

Storage

General information on storage conditions:
Keep in a dry, cool place. Keep container closed when not in use. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Store in upright position only. 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. 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. Refer also to National Fire Protection Association (NFPA) Code 400, Hazardous Materials Code.

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 bases
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.

Temperature tolerance – Do not store above:
90 °F (32 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

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:
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.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Color:	Clear - colourless
Physical state:	liquid
Odor:	slight, menthol

Odor threshold:	No data available
Flash point	180 °F (82 °C) (Method: Seta Flash Method)
Auto-ignition temperature:	No data available.
Lower flammable limit (LFL):	Not determined
Upper flammable limit (UFL):	Not determined
pH:	not determined
Density:	0.91 g/cm3 (68 °F (20 °C))
Specific Gravity (Relative density):	0.904 (77 °F(25 °C))
Vapor pressure:	approximately 27 mmHg (68 °F (20 °C))
Boiling point/boiling range:	Decomposes before boiling. Rate of decomposition increases with rising temperature.
Melting point/range:	-40 °F (-40 °C)
Freezing point:	No data available.
Evaporation rate:	No data available
Solubility in water:	insoluble
Viscosity, dynamic:	30 mPa.s 77 °F (25 °C)
Oil/water partition coefficient:	No data available.
Self-Accelerating Decomposition Temperature (SADT):	140 °F (60 °C) 35 pound container (Method: Heat Accumulation Storage Test)
Thermal decomposition:	No data available
Flammability:	See GHS Classification in Section 2

10. STABILITY AND REACTIVITY

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

Hazardous reactions:
Hazardous polymerization does not occur.

Materials to avoid:
Strong acids
Strong bases
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 SDS 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.

Data for LUPEROX® 231

Acute toxicity

Oral:
Acute toxicity estimate > 5,000 mg/kg.

Dermal:
Acute toxicity estimate > 5,000 mg/kg.

Inhalation:
4 h Acute toxicity estimate > 40 mg/l. (vapor)

Data for Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl) (6731-36-8)

Acute toxicity

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

Dermal:
No deaths occurred. (rabbit) LD0 > 2,000 mg/kg.

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

Inhalation:
No deaths occurred. (rat) 4 h LC0 > 5.6 mg/l. (aerosol)

Skin Irritation:
Causes mild skin irritation. (rabbit) Irritation Index: 2.15/8.0. (4 h)

Eye Irritation:
Causes mild eye irritation. (rabbit) Irritation Index: 1.1/110.

Skin Sensitization:
Not a sensitizer. Guinea pig maximization test. (guinea pig) No skin allergy was observed

Repeated dose toxicity
Chronic oral administration to rat / affected organ(s): Gastro-intestinal tract, lymph node, spleen, liver, kidney / signs: changes in organ structure or function, changes in organ weights, changes in blood cell counts, clinical chemistry changes

Chronic oral administration to male rat / affected organ(s): kidney / signs: hyaline droplet nephropathy / (not considered relevant in humans)

Subchronic dietary administration to mouse / affected organ(s): spleen, liver, bone marrow / signs: changes in organ weights / reduced body weight

Repeated oral administration to rat / affected organ(s): liver, kidney / signs: changes in organ structure or function, clinical chemistry changes

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

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) / No birth defects were observed.

Reproductive effects
Exposure during pregnancy. Oral (rat) / No toxicity to reproduction.

Data for Cyclohexanone, 3,3,5-trimethyl- (873-94-9)

Acute toxicity

Oral:
May be harmful if swallowed. (rat) LD50 = 3,450 mg/kg.

Dermal:
No deaths occurred. (rabbit) LD0 > 3,160 mg/kg.

Inhalation:
Harmful if inhaled. (rat) 4 h LC50 = 14.2 mg/l. (vapor)

Specific target organ toxicity - single exposure:
Irritating to respiratory system.

Skin Irritation:
Not irritating. (rabbit) Irritation Index: 0/8. (4 h) (After semi-occlusive contact)

Eye Irritation:
Causes mild eye irritation. (rabbit) Irritation Index: 5.8/110.

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

Repeated dose toxicity
Inhalation administration to rat / affected organ(s): liver, lung / signs: changes in organ weights

Genotoxicity

Assessment in Vitro:
No genetic changes were observed in a laboratory test using: bacteria, animal cells

Genetic changes were observed in a laboratory test using: human cells

Genotoxicity

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

Human experience
General:
Irritating to eyes, respiratory system and skin.

Data for Hydroperoxide, 1,1-dimethylethyl (75-91-2)

Acute toxicity

Oral:
Harmful if swallowed. (rat) LD50 = 560 mg/kg. (70 %)

Dermal:
Toxic in contact with skin. (rabbit) LD50 = 440 - 553 mg/kg. (70 %) (as aqueous solution)

Inhalation:
Fatal if inhaled. (rat) 4 h LC50 = 1.85 mg/l (503 ppm). (vapor)

Skin Irritation:
Causes severe skin burns. (rabbit) (24 h) (70 %) (occluded exposure, aqueous solution)

Causes mild skin irritation. (guinea pig) (6 h) (5 %) (aqueous solution)

Eye Irritation:
Causes serious eye damage. (rabbit) (70 %) (aqueous solution)

Skin Sensitization:
May cause an allergic skin reaction. Guinea pig maximization test. (guinea pig) Skin allergy was observed. (Strong sensitizer)

Repeated dose toxicity
Repeated inhalation administration to rat / affected organ(s): nose / signs: changes in body weight, irritation / (vapor)

Repeated oral administration to rat / affected organ(s): stomach / signs: severe irritation

Genotoxicity

Assessment in Vitro:
Genetic changes were observed in laboratory tests using: bacteria, animal cells

Genotoxicity

Assessment in Vivo:
Both positive and negative responses for genetic changes were observed in laboratory tests using: mice

No genetic changes were observed in laboratory tests using: rats

Developmental toxicity
Exposure during pregnancy. oral (rat) / No birth defects were observed. (at doses that produce effects in mothers)

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

12. ECOLOGICAL INFORMATION

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

Data for Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl) (6731-36-8)

Biodegradation:
Not readily biodegradable. (112 d) biodegradation 37 %

Bioaccumulation:
56 d BCF = 3,500 - 123,200 (Carp)

Octanol Water Partition Coefficient:
log Pow: = 7.56

Data for Cyclohexanone, 3,3,5-trimethyl- (873-94-9)

Biodegradation:
Readily biodegradable. (28 d) 59 %

Octanol Water Partition Coefficient:
log Pow: = 2.6

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

Data for Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl) (6731-36-8)

Aquatic toxicity data:
No effect up to the limit of solubility. Danio rerio (zebra fish) 96 h LC50 > 0.043 mg/l (nominal concentrations reported)

Aquatic invertebrates:
No effect up to the limit of solubility. Daphnia magna (Water flea) 48 h EC50 = 0.133 mg/l (nominal concentrations reported)

Microorganisms:
Activated sludge 3 h EC10 (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 (Reproduction inhibition) = 15 mg/l (Nominal concentration)

Chronic toxicity to aquatic plants:
No effect up to the limit of solubility. Pseudokirchneriella subcapitata (green algae) 72 h NOEC = 0.18 mg/l (Nominal concentration)

Data for Cyclohexanone, 3,3,5-trimethyl- (873-94-9)

Aquatic toxicity data:
Practically nontoxic. Danio rerio (zebra fish) 96 h LC0 > 100 mg/l (Nominal concentration)

Aquatic invertebrates:
Practically nontoxic. Daphnia magna (Water flea) 48 h EC50 = 180 mg/l

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

Microorganisms:
Activated sludge 3 h EC50 = 755 mg/l

13. DISPOSAL CONSIDERATIONS

Waste disposal:
Dilution followed by incineration is the preferred method. Dilution ratio of 10:1 in a clean, compatible, combustible solvent (i.e., Fuel Oil #2, mineral oil) will reduce reactivity hazard during incineration and transportation. 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)

UN Number	:	3101
Proper shipping name	:	Organic peroxide type B, liquid
Technical name	:	(1,1-Di(tert-butylperoxy)-3,3,5-trimethylcyclohexane, > 90-100%)
Class	:	5.2
Subsidiary hazard class	:	(1)
Marine pollutant	:	no

International Maritime Dangerous Goods Code (IMDG)

UN Number	:	3101
Proper shipping name	:	ORGANIC PEROXIDE TYPE B, LIQUID
Technical name	:	(1,1-DI-(TERT-BUTYLPEROXY)-3,3,5-TRIMETHYLCYCLOHEXANE, > 90-100%)
Class	:	5.2
Marine pollutant	:	no
Flash point	:	180 °F (82 °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 Canadian DSL
China. Inventory of Existing Chemical Substances in China (IECSC)	IECSC (CN)	Conforms to
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Conforms to
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Conforms to

Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Conforms to
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	Conforms to
Australia Inventory of Chemical Substances (AICS)	AICS	Conforms to

United States – Federal Regulations

SARA Title III – Section 302 Extremely Hazardous Chemicals:
The components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.

SARA Title III - Section 311/312 Hazard Categories:
Fire Hazard, Reactivity Hazard, 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):

Chemical name	CAS-No.	Reportable quantity
Hydroperoxide, 1,1-dimethylethyl	75-91-2	100 lbs

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 name	CAS-No.
Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl)	6731-36-8
Cyclohexanone, 3,3,5-trimethyl-	873-94-9

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.

H226	Flammable liquid and vapour.
H227	Combustible liquid.
H241	Heating may cause a fire or explosion.
H242	Heating may cause a fire.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H411	Toxic 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:	200014272
Date of Revision:	08/11/2017
Date Printed:	08/12/2017

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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.