

RILSAN® 5510 GREY RDP 15-10 ES**1. PRODUCT AND COMPANY IDENTIFICATION****Company**

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

Specialty Polyamides

Customer Service Telephone Number: (800) 932-0420
(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: RILSAN® 5510 GREY RDP 15-10 ES
Synonyms: Not available
Molecular formula: Not available
Chemical family: polyamide
Product use: coating agent

2. HAZARDS IDENTIFICATION**Emergency Overview**

Color: grey
Physical state: solid
Form: powder
Odor: none

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

Chronic aquatic toxicity, Category 3, H412

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

GHS-Labeling

Signal word: **Warning**

Hazard statements:

H412 : Harmful to aquatic life with long lasting effects.

Supplemental Hazard Statements:

May form combustible dust concentrations in air.
Processing may release vapors and/or fumes which cause eye, skin and respiratory tract irritation.

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Precautionary statements:

Prevention:

P273 : Avoid release to the environment.

Disposal:

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

Supplemental information:

Potential Health Effects:

The product, in the form supplied, is not anticipated to produce significant adverse human health effects. Contains high molecular weight polymer(s). Effects due to processing releases: Irritating to eyes, respiratory system and skin.

Prolonged or repeated exposure may cause: headache, drowsiness, nausea, weakness, (severity of effects depends on extent of exposure).

Other:

Handle in accordance with good industrial hygiene and safety practice. (powder) Mechanical irritation effects from dust exposure are possible at ambient temperature. This product may release fume and/or vapor of variable composition depending on processing time and temperature. This material may contain residual caprolactam monomer.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Undecanoic acid, 11-amino-, homopolymer	25587-80-8	>= 75 %	Not classified
Hexanedioic acid, polymer with azacyclotridecan-2-one, hexahydro-2H-azepin-2-one and 1,6-hexanediamine	26777-62-8	< 10 %	Not classified
Carbonic acid calcium salt (1:1)	471-34-1	< 10 %	Not classified
Water	7732-18-5	< 2 %	Not classified

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Titanium oxide (TiO ₂)	13463-67-7	< 5 %	Not classified
Proprietary component	Proprietary*	<= 0.5 %	H400, H410

*The specific chemical identity is withheld because it is trade secret information of Arkema Inc.

**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. If molten polymer gets on the skin, cool rapidly with cold water. Do not peel solidified product off the skin. Obtain medical treatment for thermal burns. Remove material from clothing. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eyes:

Immediately flush eye(s) with plenty of water. Obtain medical treatment for thermal burns.

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

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

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(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.

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.

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

Carbon oxides

Hazardous organic compounds

Hydrogen cyanide (hydrocyanic acid)

(traces)

Nitrogen 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.

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Avoid breathing dust.
Keep away from heat, sparks and flames.
Keep container closed.
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.
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.

Storage**General information on storage conditions:**

Keep in a dry, cool place. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Store away from moisture and heat to maintain the technical properties of the product. 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. 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:

Stable under normal conditions.

Storage incompatibility – General:

None known.

Temperature tolerance – Do not store above:

140 °F (60 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Airborne Exposure Guidelines:****Carbonic acid calcium salt (1:1) (471-34-1)**

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

Form:

Respirable fraction.

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PEL: 5 mg/m3

Form: Total dust
PEL: 15 mg/m3**Titanium oxide (TiO₂) (13463-67-7)**

US. ACGIH Threshold Limit Values

Time weighted average 10 mg/m3

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

Form: Total dust
PEL: 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 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 and substances released during processing. 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:

Processing of this product releases vapors or fumes which may cause skin irritation. Minimize skin contamination by following good industrial hygiene practice. Wearing protective gloves is recommended. Wash hands and contaminated skin thoroughly after contact with processing fumes or vapors. Wash thoroughly after handling.

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Eye protection:

Use good industrial practice to avoid eye contact. Processing of this product releases vapors or fumes which may cause eye irritation. Where eye contact may be likely, wear chemical goggles and have eye flushing equipment available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color:	grey
Physical state:	solid
Form:	powder
Odor:	none
Odor threshold:	No data available
Flash point	No data available
Auto-ignition temperature:	No data available
Lower flammable limit (LFL):	Not applicable
Upper flammable limit (UFL):	Not applicable
pH:	No data available
Density:	No data available
Specific Gravity (Relative density):	1.0 - 1.3
Vapor pressure:	No data available
Vapor density:	No data available
Boiling point/boiling range:	No data available
Melting point/range:	363 - 378 °F (184 - 192 °C)
Freezing point:	No data available
Evaporation rate:	No data available
Solubility in water:	negligible
Solubility in other solvents: [qualitative and quantitative]	Insoluble in most organic solvents

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Viscosity, dynamic:	No data available.
Oil/water partition coefficient:	No data available
Thermal decomposition	< 662 °F (< 350 °C)
Flammability:	See GHS Classification in Section 2

10. STABILITY AND REACTIVITY**Stability:**

The product is stable under normal handling and storage conditions.

Hazardous reactions:

Hazardous polymerization does not occur.

Materials to avoid:

None known.

Conditions / hazards to avoid:

Store protected from moisture and heat. (to maintain the technical properties of the product). See Hazardous Decomposition Products below.

Hazardous decomposition products:

Thermal decomposition giving toxic, flammable, and / or corrosive products:

Carbon oxides

Ammonia

Hydrogen cyanide (hydrocyanic acid)
(traces)

Hazardous organic compounds

Amine derivatives

Nitrogen compounds

11. TOXICOLOGICAL INFORMATION

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

Data for Undecanoic acid, 11-amino-, homopolymer (25587-80-8)**Acute toxicity****Oral:**

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

Dermal:

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

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Skin Irritation:

Not irritating. (In vitro)

Eye Irritation:

Not corrosive (Bovine cornea)

Skin Sensitization:

Not a sensitizer. LLNA: Local Lymph Node Assay. (Mouse) No effect is reported.

Repeated dose toxicity

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

Genotoxicity**Assessment in Vitro:**

No genetic changes were observed in laboratory tests using: bacteria

Other information

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

Data for Carbonic acid calcium salt (1:1) (471-34-1)**Acute toxicity****Oral:**

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

Dermal:

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

Inhalation:

No deaths occurred. (rat) 4 h LC₀ > 3 mg/l. (dust/mist, Maximum concentration technically possible)

Skin Irritation:

Not irritating. (rabbit) Irritation Index: 0.0 / 8.0. (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

Repeated dose toxicity

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

Genotoxicity**Assessment in Vitro:**

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

Developmental toxicity

Exposure during pregnancy. Oral (sheep) / bone effects in lambs (at doses that produce effects in mothers,

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blood chemistry changes)

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

Reproductive effects

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

Human experience**General:**

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin.

Human experience**Inhalation:**

Upper respiratory tract: Local irritation, coughing. (dust) (severity of effects depends on extent of exposure)

Human experience**Ingestion:**

Kidney: failure, weakness, nausea. (effects of excessive exposure)

Data for Titanium oxide (TiO₂) (13463-67-7)**Acute toxicity****Oral:**

Practically nontoxic. (rat) LC50 > 5,000 mg/kg.

Dermal:

Practically nontoxic. (rabbit) LD50 > 10,000 mg/kg.

Inhalation:

Practically nontoxic. (rat) 4 h LC50 > 6.82 mg/l. (dust/mist)

Skin Irritation:

Practically non-irritating. (rabbit) Irritation Index: 0 - 0.28/8.0.

Eye Irritation:

Causes mild eye irritation. (rabbit)

Skin Sensitization:

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

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

Repeated dose toxicity

Subchronic inhalation administration to rat / affected organ(s): respiratory tract / Local irritation of the respiratory system

Subchronic oral administration to rat / No adverse effects reported.

Carcinogenicity

Chronic dietary administration to rat and mouse / signs: No increase in tumor incidence was reported.

Chronic inhalation administration to rat / affected organ(s): lung / signs: Increase in tumor incidence was reported.

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Classified by the International Agency for Research on Cancer as: Group 2B: Possibly carcinogenic to humans.

Genotoxicity**Assessment in Vitro:**

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

Genotoxicity**Assessment in Vivo:**

No genetic changes were observed in laboratory tests using: mice, rats

Developmental toxicity

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

Human experience**Skin contact:**

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

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

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

Data for Proprietary component (Proprietary)**Biodegradation:**

Not readily biodegradable. (aerobic, 28 d) biodegradation 4.5 %

Bioaccumulation:

56 d BCF = 280 - 2,500 (Cyprinus carpio (Carp))

Octanol Water Partition Coefficient:

log Pow = 5.1

Ecotoxicology

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

Data for Carbonic acid calcium salt (1:1) (471-34-1)**Aquatic toxicity data:**

No effect up to the limit of solubility. Oncorhynchus mykiss (rainbow trout) 96 h LC50 > 100 mg/l

Aquatic invertebrates:

No effect up to the limit of solubility. Daphnia magna (Water flea) 48 h EC50 > 100 mg/l

Algae:

No effect up to the limit of solubility. Desmodesmus subspicatus (green algae) 72 h EC50 > 14 mg/l

Microorganisms:

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

Data for Titanium oxide (TiO2) (13463-67-7)

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

Aquatic toxicity data:

No effect up to the limit of solubility. Oncorhynchus mykiss (rainbow trout) 96 h LC50 > 100 mg/l (Nominal concentration)

No effect up to the limit of solubility. Pimephales promelas (fathead minnow) 96 h LC50 > 1,000 mg/l (Nominal concentration)

Aquatic invertebrates:

No effect up to the limit of solubility. Daphnia magna (Water flea) 96 h EC50 > 100 mg/l (Nominal concentration)

Algae:

Harmful. Pseudokirchneriella subcapitata (green algae) 72 h EC50 = 61 mg/l (Nominal concentration)

Microorganisms:

Practically nontoxic. Pseudomonas fluorescens 24 h EC50 > 10,000 mg/l

Practically nontoxic. Activated sludge 3 h EC50 > 1,000 mg/l

Data for Proprietary component (Proprietary)**Aquatic toxicity data:**

No effect up to the limit of solubility. Brachydanio rerio (zebrafish) 96 h LC0 >= 0.57 mg/l

Aquatic invertebrates:

Very toxic. Daphnia magna (Water flea) 48 h EC50 = 0.61 mg/l

Algae:

No effect up to the limit of solubility. Desmodesmus subspicatus (green algae) 72 h EC50 > 0.42 mg/l

Microorganisms:

No effect up to the limit of solubility. Pseudomonas putida 30 min EC0 = 500 mg/l

Chronic toxicity to aquatic invertebrates:

Very toxic. Daphnia magna (Water flea) 21 d NOEC (reproduction) = 0.023 mg/l

13. DISPOSAL CONSIDERATIONS**Waste disposal:**

Where possible recycling is preferred to disposal or incineration. If recycling is not an option, incinerate or dispose of in accordance with federal, state, and local regulations. Pigmented, filled and/or solvent laden product may require special disposal practices 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.

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14. TRANSPORT INFORMATION

US Department of Transportation (DOT): not regulated

International Maritime Dangerous Goods Code (IMDG): not regulated

15. REGULATORY INFORMATION
Chemical Inventory Status

EU. EINECS	EINECS	Conforms to
United States TSCA Inventory	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)	Does not conform
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

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):

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

United States – State Regulations
New Jersey Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
Carbonic acid calcium salt (1:1)	471-34-1
Titanium oxide (TiO ₂)	13463-67-7

Pennsylvania Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
Undecanoic acid, 11-amino-, homopolymer	25587-80-8
Hexanedioic acid, polymer with azacyclotridecan-2-one, hexahydro-2H-azepin-2-one and 1,6-hexanediamine	26777-62-8
Carbonic acid calcium salt (1:1)	471-34-1
Titanium oxide (TiO ₂)	13463-67-7

California Prop. 65

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

<u>Chemical name</u>	<u>CAS-No.</u>
Carbon black	1333-86-4
Lead	7439-92-1
Nickel	7440-02-0
Arsenic	7440-38-2
Cadmium	7440-43-9
Titanium oxide (TiO ₂)	13463-67-7
Quartz (SiO ₂)	14808-60-7

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

<u>Chemical name</u>	<u>CAS-No.</u>
Lead	7439-92-1
Mercury	7439-97-6
Cadmium	7440-43-9

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16. OTHER INFORMATION

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

H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

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: 000000035159
Date of Revision: 11/10/2016
Date Printed: 11/16/2016

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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.