

1. PRODUCT AND COMPANY IDENTIFICATION**Company**

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

Arkema Coating Resins

Customer Service Telephone Number: (877) 331-6696
(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: CRAYVALLAC® WN-1150
Synonyms: Not available
Molecular formula: Not available
Chemical family: Micronized wax
Product use: Additive for :Paints

2. HAZARDS IDENTIFICATION**Emergency Overview**

Color: off-white
Physical state: solid
Form: powder
Odor: none

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

Skin sensitisation, Category 1, H317
Chronic aquatic toxicity, Category 2, H411

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

GHS-Labeling

Hazard pictograms:



Signal word: **Warning**

Hazard statements:

H317 : May cause an allergic skin reaction.
H411 : Toxic to aquatic life with long lasting effects.

Supplemental Hazard Statements:

May form combustible dust concentrations in air.

Precautionary statements:

Prevention:

P261 : Avoid breathing gas/mist/vapours/spray.
P272 : Contaminated work clothing should not be allowed out of the workplace.
P273 : Avoid release to the environment.
P280 : Wear protective gloves.

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.
P391 : Collect spillage.

Disposal:

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

Supplemental information:

Potential Health Effects:

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Paraffin waxes and Hydrocarbon waxes	8002-74-2	>= 85 %	Not classified
2(3H)-Benzothiazolethione, zinc salt (2:1)	155-04-4	< 15 %	H317, H400, H410
2(3H)-Benzothiazolethione	149-30-4	< 2 %	H317, H400, H410

**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

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.

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:

CRAYVALLAC® WN-1150

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

Carbon oxides

Hazardous organic compounds

Sulphur oxides

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.

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:**

Avoid breathing dust.

Avoid prolonged or repeated contact with skin.

Keep away from heat, sparks and flames.

Keep container closed.

Wash thoroughly after handling.

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.

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.

Follow label warnings even after container is emptied.

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 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 incompatibility – General:

Store separate from:

Strong oxidizing agents

Temperature tolerance – Do not store above:

100 °F (38 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Paraffin waxes and Hydrocarbon waxes (8002-74-2)

US. ACGIH Threshold Limit Values

Form:	Fumes
Time weighted average	2 mg/m ³

2(3H)-Benzothiazolethione (149-30-4)

US. OARS. WEELs Workplace Environmental Exposure Level Guide

Time weighted average	5 mg/m ³
-----------------------	---------------------

Skin designation

Remarks: Can be absorbed through the skin.

Remarks: Listed

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. Provide a safety shower at any location where skin contact can occur. Wash thoroughly after handling.

Eye protection:

Use good industrial practice to avoid eye contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color:	off-white
Physical state:	solid
Form:	powder
Odor:	none
Odor threshold:	No data available
Flash point	Not applicable
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

Vapor pressure:	No data available
Vapor density:	No data available
Boiling point/boiling range:	No data available
Melting point/range:	No data available
Freezing point:	No data available
Evaporation rate:	No data available
Solubility in water:	20.6 mg/l 6.3 68 °F (20 °C) (data for 2(3H)-Benzothiazolethione, zinc salt (2:1) (155-04-4))
Viscosity, dynamic:	No data available
Oil/water partition coefficient:	No data available
Thermal decomposition	No data available
Flammability:	See GHS Classification in Section 2

10. STABILITY AND REACTIVITY

Stability:

This material is chemically stable under normal and anticipated storage, handling and processing conditions.

Hazardous reactions:

Hazardous polymerisation does not occur.

Materials to avoid:

Strong oxidizing agents

Conditions / hazards to avoid:

Keep away from heat and sources of ignition. Keep in a dry place.

Hazardous decomposition products:

Thermal decomposition giving flammable and toxic products :

Carbon oxides

Hazardous organic compounds

Sulphur oxides

11. TOXICOLOGICAL INFORMATION

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

Oral:

Acute toxicity estimate > 5,000 mg/kg.

Data for Paraffin waxes and Hydrocarbon waxes (8002-74-2)**Acute toxicity****Oral:**

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

Dermal:

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

Skin Irritation:

Practically non-irritating. (Rabbit) Irritation Index: ≤ 1.5 / 8. (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 dietary administration to rat / affected organ(s): liver, lymph node, heart / signs: changes in blood cell counts, clinical chemistry changes, changes in organ weights, changes in organ structure or function

Carcinogenicity

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

Chronic dermal administration to mouse / signs: No increase in tumor incidence was reported.

Genotoxicity**Assessment in Vitro:**

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

Human experience**Inhalation:**

Upper respiratory tract: chest discomfort, irritation. (releases from hot processing) (dust or fume) (based on reports of occupational exposure to workers)

Human experience**Ingestion:**

Gastro-intestinal tract: nausea, cramps, diarrhea. (severity of effects depends on extent of exposure)

Data for 2(3H)-Benzothiazolethione, zinc salt (2:1) (155-04-4)**Acute toxicity****Oral:**

Practically nontoxic. (rat) LD₅₀ = 7,500 mg/kg.

Dermal:

Practically nontoxic (rabbit) LD₀ > 7,940 mg/kg.

Skin Irritation:

Not irritating. (rabbit) Irritation Index: 0/8. (24 h)

Eye Irritation:

Causes mild eye irritation. (rabbit)

Skin Sensitization:

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

Carcinogenicity

Chronic dietary administration to mice / signs: No increase in tumor incidence was reported.

Genotoxicity**Assessment in Vitro:**

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

Genotoxicity**Assessment in Vivo:**

No genetic changes were observed in laboratory tests using: mice

Data for 2(3H)-Benzothiazolethione (149-30-4)**Acute toxicity****Oral:**

Slightly toxic (rat) LD₅₀ = 3,800 mg/kg.

Dermal:

Practically nontoxic. (rabbit) LD₀ > 7,940 mg/kg.

Inhalation:

No deaths occurred. (rat) 4 h LC₀ > 1.27 mg/l.

Skin Irritation:

Not irritating. (rabbit) Irritation Index: 0/8.

Eye Irritation:

Causes mild eye irritation. (rabbit) Irritation Index: 3.2/110.

Skin Sensitization:

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

Repeated dose toxicity

Chronic oral administration to rat / affected organ(s): kidney, forestomach / signs: changes in organ structure or function

Carcinogenicity

Chronic oral administration to mouse / signs: No increase in tumor incidence was reported.

Chronic oral administration to rat / affected organ(s): Pituitary gland, adrenal gland / signs: Increase in tumor incidence was reported.

Genotoxicity**Assessment in Vitro:**

No genetic changes were observed in laboratory tests using: bacteria

No genetic changes were observed in a laboratory test using: animal cells

An equivocal response has been reported in a test using: animal cells

Genotoxicity**Assessment in Vivo:**

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

Developmental toxicity

Exposure during pregnancy. oral (rabbit, rat) / No birth defects were observed.

Reproductive effects

Two-generation study. dietary (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 Paraffin waxes and Hydrocarbon waxes (8002-74-2)**Biodegradation:**

Inherently biodegradable. (28 d) biodegradation 78 - 84 %

Data for 2(3H)-Benzothiazolethione, zinc salt (2:1) (155-04-4)**Biodegradation:**

Not readily biodegradable. (35 d) biodegradation 2 %

Octanol Water Partition Coefficient:

log Pow = 2.42

Additional Information:

Information given is based on data obtained from similar substances.

Data for 2(3H)-Benzothiazolethione (149-30-4)**Biodegradation:**

Not readily biodegradable. (35 d) biodegradation 2 %

Octanol Water Partition Coefficient:

log Pow = 2.42

Ecotoxicology

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

Data for 2(3H)-Benzothiazolethione, zinc salt (2:1) (155-04-4)

Information given is based on data obtained from similar substances.

Aquatic toxicity data:

Very toxic. Oncorhynchus mykiss (rainbow trout) 96 h LC50 = 0.73 mg/l

Aquatic invertebrates:

Very toxic. Daphnia magna (Water flea) 48 h EC50 = 0.71 mg/l

Algae:

Very toxic. Pseudokirchneriella subcapitata (green algae) 72 h ErC50 = 0.5 mg/l

Microorganisms:

Respiration inhibition / Activated sludge 3 h EC50 = 1,220 mg/l

Chronic toxicity to fish:

Very toxic. Oncorhynchus mykiss (rainbow trout) 89 d NOEC = 0.041 mg/l

Chronic toxicity to aquatic invertebrates:

Very toxic. Daphnia magna (Water flea) 21 d NOEC (reproduction) = 0.08 mg/l

Chronic toxicity to aquatic plants:

Very toxic. Pseudokirchneriella subcapitata (green algae) 72 h NOEC (reproduction) = 0.066 mg/l

Data for 2(3H)-Benzothiazolethione (149-30-4)**Aquatic toxicity data:**

Very toxic. Oncorhynchus mykiss (rainbow trout) 96 h LC50 = 0.73 mg/l

Aquatic invertebrates:

Very toxic. Daphnia magna (Water flea) 48 h EC50 = 0.71 mg/l

Algae:

Very toxic. Pseudokirchneriella subcapitata (green algae) 72 h ErC50 = 0.5 mg/l

Microorganisms:

Respiration inhibition / Activated sludge 3 h EC50 = 3,301 mg/l

Chronic toxicity to fish:

Very toxic. Oncorhynchus mykiss (rainbow trout) 89 d NOEC = 0.041 mg/l

Chronic toxicity to aquatic invertebrates:

Very toxic. Daphnia magna (Water flea) 21 d NOEC (reproduction) = 0.08 mg/l

Chronic toxicity to aquatic plants:

Very toxic. Pseudokirchneriella subcapitata (green algae) 72 h NOEC (reproduction) = 0.066 mg/l

13. DISPOSAL CONSIDERATIONS

Waste disposal:

Disposal via incineration is recommended. Dispose of in accordance with federal, state and local regulations. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits. Note: Chemical additions to, processing of, or otherwise altering this material may make this waste management information incomplete, inaccurate, or otherwise inappropriate. Furthermore, state and local waste disposal requirements may be more restrictive or otherwise different from federal laws and regulations.

Take appropriate measures to prevent release to the environment.

14. TRANSPORT INFORMATION

US Department of Transportation (DOT)

UN Number : 3077
Proper shipping name : Environmentally hazardous substances, solid, n.o.s.
Technical name : (Benzothiazole-2-thiol, Zinc di(benzothiazol-2-yl) disulphide)
Class : 9
Packaging group : III
Marine pollutant : yes

International Maritime Dangerous Goods Code (IMDG)

UN Number : 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Technical name : (BENZOTHAZOLE-2-THIOL, ZINC DI(BENZOTHAZOL-2-YL) DISULPHIDE)
Class : 9
Packaging group : III
Marine pollutant : yes

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

SAFETY DATA SHEET

CRAYVALLAC® WN-1150

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:

Acute Health Hazard

SARA Title III – Section 313 Toxic Chemicals:

The following components are subject to reporting levels established by SARA Title III, Section 313:

<u>Chemical name</u>	<u>CAS-No.</u>	<u>De minimis concentration</u>	<u>Reportable threshold:</u>
2(3H)-Benzothiazolethione	149-30-4	1.0 %	25000 lbs (Manufacturing and processing) 10000 lbs (Otherwise used (non-manufacturing/processing))
2(3H)-Benzothiazolethione, zinc salt (2:1)	155-04-4	1.0 %	25000 lbs (Manufacturing and processing) 10000 lbs (Otherwise used (non-manufacturing/processing))

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):

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

United States – State Regulations

New Jersey Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
Paraffin waxes and Hydrocarbon waxes	8002-74-2
2(3H)-Benzothiazolethione, zinc salt (2:1)	155-04-4

CRAYVALLAC® WN-1150

2(3H)-Benzothiazolethione

149-30-4

Pennsylvania Right to Know

Chemical name

Paraffin waxes and Hydrocarbon waxes

CAS-No.

8002-74-2

2(3H)-Benzothiazolethione, zinc salt (2:1)

155-04-4

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.

H317 May cause an allergic skin reaction.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic 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: 000000093774
Date of Revision: 05/06/2016
Date Printed: 07/27/2016

CRAYVALLAC® is a registered trademark of Arkema Inc.

The statements, technical information and recommendations contained herein are believed to be accurate as of the date hereof. Since the conditions and methods of use of the product and of the information referred to herein are beyond our control, ARKEMA expressly disclaims any and all liability as to any results obtained or arising from any use of the product or reliance on such information; **NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE GOODS DESCRIBED OR THE INFORMATION PROVIDED HEREIN.** The information provided herein relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. The user should thoroughly test any application before commercialization. Nothing contained herein constitutes a license to practice under any patent and it should not be construed as an inducement to infringe any patent and the user is advised to take appropriate steps to be sure that any proposed use of the product will not result in patent infringement. See SDS for Health & Safety Considerations.

Arkema has implemented a Medical Policy regarding the use of Arkema products in Medical Devices applications that are in contact with the body or circulating bodily fluids (<http://www.arkema.com/en/social-responsibility/responsible-product-management/medical-device-policy/index.html>) Arkema has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by Arkema for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, Arkema strictly prohibits the use of any Arkema products in Medical

CRAYVALLAC® WN-1150

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.