

CRAYVALLAC® LA-250

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® LA-250

Synonyms: Not available Molecular formula: Complex Mixture

Chemical family: MODIFIED UREA SOLUTION

Product use: Additive for:, Paints, Coatings, Inks, Adhesives

2. HAZARDS IDENTIFICATION

Emergency Overview

Color: light yellow Physical state: liquid

Odor: solvent-like, sulphurous

*Classification of the substance or mixture:

Flammable liquids, Category 4, H227 Chronic aquatic toxicity, Category 4, H413

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

GHS-Labelling

Signal word: Warning

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Hazard statements:

H227 : Combustible liquid.

H413: May cause long lasting harmful effects to aquatic life.

Supplemental Hazard Statements:

For research and development use only by technically qualified individuals under section 5(h)(3) of the Toxic Substances Control Act.

Precautionary statements:

Prevention:

P210: Keep away from heat, sparks, open flames, hot surfaces. No smoking.

P273: Avoid release to the environment.

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

Response:

P370 + P378 : In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

Storage:

P403 + P235 : Store in a well-ventilated place. Keep cool.

Disposal:

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

Supplemental information:

Potential Health Effects:

Can be absorbed through the skin. Prolonged or repeated contact may dry skin and cause irritation. Prolonged or repeated exposure may cause: Strong garlic-like odor of the breath

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Methane, sulfinylbis-	67-68-5	>= 30 - < 60 %	Not classified
Proprietary modified urea	Proprietary*	>= 30 - < 60 %	H413



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

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 if applicable) 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).

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

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Further firefighting advice:

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:

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

Carbon oxides

sulfur oxides

hydrogen sulfide

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. 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:

Keep away from heat and flames.

No smoking.

Keep container closed.

Use only with adequate ventilation.

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

Follow label warnings even after container is emptied.

Observe all labeled safeguards until container is cleaned, reconditioned or destroyed.

RESIDUAL VAPORS MAY EXPLODE ON IGNITION.

DO NOT CUT, DRILL, GRIND, OR WELD ON OR NEAR THIS CONTAINER.

Emptied container retains vapor and product residue.

Storage

General information on storage conditions:

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Keep in a dry, cool place. Keep container closed when not in use. Store in upright position only. 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 OSHA 29 CFR 1910.106 and NFPA 30, 70, 77, and 497.

Storage incompatibility - General:

Store separate from:
Methylbromide
Sodium hydride
Zinc, Steel (in the presence of water)
Strong acids: perchloric acid, periodic acid
Strong oxidizing agents

Temperature tolerance - Do not store below:

68 °F (20 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Methane, sulfinylbis- (67-68-5)

US. OARS. WEELs Workplace Environmental Exposure Level Guide

Time weighted average 250 ppm

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.

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. 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

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full face positive-pressure, self-contained breathing apparatus or positive-pressure airline with auxiliary selfcontained 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. When handling this material, gloves of the following type(s) should be worn: butyl-rubber

neoprene

Wear face shield and chemical resistant clothing such as a rubber apron when splashing may occur. Rinse immediately if skin is contaminated. Wash contaminated clothing and clean protective equipment before reuse. Wash thoroughly after handling.

Eye protection:

Use good industrial practice to avoid eye contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: light yellow

Physical state: liquid

Odor: solvent-like, sulphurous

Odor threshold: No data available.

Flash point > 158 °F (70 °C) (Method: Seta Flash Method)

Auto-ignition temperature:

No data available.

Lower flammable limit

(LFL):

No data available.

Upper flammable limit

(UFL):

No data available.

pH: No data available.

Density: 1.1 g/cm3 (68 °F (20 °C))

Specific Gravity (Relative

density):

1.1 (68 °F(20 °C))Water=1 (liquid)

Vapor pressure: No data available.

Vapor density: No data available.

Boiling point/boiling

range:

No data available.

No data available. Melting point/range:

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Freezing point: No data available.

Evaporation rate: No data available.

Solubility in water: miscible

Viscosity, dynamic: 300 - 700 mPa.s 77 °F (25 °C) (Method: ISO 3219)

Oil/water partition

coefficient:

No data available.

Thermal decomposition: No data available.

Flammability: See GHS Classification in Section 2 if applicable

10. STABILITY AND REACTIVITY

Stability:

This material is chemically stable under normal and anticipated storage, handling and processing conditions. Stability of the solution decreases under the action of heat, light, and in the presence of impurities

Hazardous reactions:

Hazardous polymerization does not occur.

Materials to avoid:

Methylbromide Sodium hydride Zinc, Steel (in the presence of water) Strong acids: perchloric acid, periodic acid Strong oxidizing agents

Conditions / hazards to avoid:

Keep away from heat and sources of ignition. To avoid thermal decomposition, do not overheat.

Hazardous decomposition products:

Thermal decomposition giving flammable and toxic products Carbon oxides sulfur oxides hydrogen sulfide 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 Methane, sulfinylbis- (67-68-5)

Acute toxicity

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Oral:

Practically nontoxic. (rat) LD50 = 28,300 mg/kg.

Dermal:

Practically nontoxic. (rat) LD50 = 40,000 mg/kg.

Inhalation:

Practically nontoxic. (rat) 4 h LC0 > 5.3 mg/l. (dust/mist)

Skin Irritation:

Practically non-irritating. (rabbit)

Eye Irritation:

Causes mild eye irritation. (rabbit)

Skin Sensitization:

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

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

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

Repeated dose toxicity

Subchronic inhalation administration to rat / Local irritation of the respiratory system

Subchronic dermal administration to rabbit / affected organ(s): eye / signs: changes in organ structure or function / (Repeated exposure at high concentrations)

Subchronic dermal administration to dog / affected organ(s): eye / signs: changes in organ structure or function / (Repeated exposure at high concentrations)

Chronic oral administration to rat and dog / affected organ(s): eye / signs: changes in organ structure or function / (Repeated exposure at high concentrations)

Oral, dermal administration to monkey / signs: Gastrointestinal disturbance, Garlic smell on breath / No adverse systemic effects reported.

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, fruit flies, rats, (data for similar material)

Developmental toxicity

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

Reproductive effects

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

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Human experience

General:

Rapidly absorbed through skin.

Human experience

Skin contact:

Skin: dry skin, dermatitis, rash, redness. (repeated or prolonged exposure)

Systemic effects: Strong garlic-like odor of the breath, headache, eye pain, fatigue, dizziness.

Skin: No skin allergy was observed.

Human experience

Eye contact:

Eyes: stinging, tearing.

Data for Proprietary modified urea (Proprietary)

Acute toxicity

Oral:

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

Inhalation:

Practically nontoxic. (rat) 4 h LC50 > 5.25 mg/l. (dust/mist)

Skin Irritation:

Not irritating. (In vitro) EPISKIN Human Skin Model Test

Eye Irritation:

Not irritating. (In vitro) Bovine corneal opacity and permeability assay (BCOP)

Skin Sensitization:

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

Repeated dose toxicity

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

Repeated inhalation administration to rat / affected organ(s): lung, lymph node / signs: 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) / No toxicity to reproduction.

Data for Stabilizer (Proprietary)

Acute toxicity

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Oral:

Harmful if swallowed. (rat) LD50 = 526 mg/kg.

Harmful if swallowed. (mouse) LD50 = 1,165 mg/kg.

Dermal:

No deaths occurred. (rat) LD50 > 2,000 mg/kg.

Inhalation:

Practically nontoxic. (rat) 4 h LC50 > 5.57 mg/l. (dust/mist)

Skin Irritation:

Causes skin irritation. (rabbit) (4 h)

Eye Irritation:

Causes eye irritation. (rabbit)

Skin Sensitization:

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

Repeated dose toxicity

Repeated dietary administration to rat / affected organ(s): Thyroid gland, reproductive system / signs: atrophy, changes in body weight, decreased growth rate / Repeated exposure at high concentrations

Chronic drinking water administration to rat / signs: At high concentrations, tremors, loss of muscle coordination, decreased growth rate, death

Chronic oral administration to dog / affected organ(s): kidney

Genotoxicity

Assessment in Vitro:

No genetic changes were observed in laboratory tests using: bacteria, human cells, animal cells, (data for a similar material)

Developmental toxicity

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

Exposure during pregnancy. oral (rat) / No birth defects were observed. (at doses that produce effects in mothers, data for a similar material)

12. ECOLOGICAL INFORMATION

Chemical Fate and Pathway

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

Data for Methane, sulfinylbis- (67-68-5)

Biodegradation:

Not readily biodegradable. (28 d) Water 31 %

Bioaccumulation:

Not expected to bioaccumulate.

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Octanol Water Partition Coefficient:

log Pow: = -1.35(Does not bioaccumulate.)

Data for Proprietary modified urea (Proprietary)

Biodegradation:

Not readily biodegradable. (28 d) biodegradation 2 %

Octanol Water Partition Coefficient:

log Pow: > 6, at 77 °F (25 °C)

Ecotoxicology

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

Data for Methane, sulfinylbis- (67-68-5)

Aquatic toxicity data:

Practically nontoxic. Danio rerio (zebra fish) 96 h LC50 > 25,000 mg/l

Aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 48 h EC50 = 24,600 mg/l

Algae:

Practically nontoxic. Pseudokirchneriella subcapitata (microalgae) 72 h EC50 = 17,000 mg/l

Microorganisms:

Respiration inhibition / Activated sludge 30 min EC50 = 10 - 100 mg/l Microtox test / Photobacterium phosphoreum 5 min EC50 = 77 mg/l Cell multiplication inhibition test / Pseudomonas putida 16 h EC50 = 16,000 mg/l

Chronic toxicity to aquatic plants:

Practically nontoxic. Algae 14 d LC50 = 390 - 4020 mg/l

Data for Proprietary modified urea (Proprietary)

Aquatic toxicity data:

No effect up to the limit of solubility. Danio rerio (zebra fish) 96 h LC50 > 100 mg/l (Nominal concentration, Water accommodated fraction was tested.)

Aquatic invertebrates:

No effect up to the limit of solubility. Daphnia magna (Water flea) EL50 > 1,000 mg/l (Nominal concentration, Water accommodated fraction was tested.)

Algae:

No effect up to the limit of solubility. Pseudokirchneriella subcapitata (green algae) 72 h EL50 > 100 mg/l (Water accommodated fraction was tested.)

Chronic toxicity to aquatic invertebrates:

No effect up to the limit of solubility. Daphnia magna (Water flea) 21 d EL10 (reproduction) > 100 mg/l (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 > 100 mg/l

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(Water accommodated fraction was tested.)

Data for Stabilizer (Proprietary)

Aquatic toxicity data:

Practically nontoxic. Oncorhynchus mykiss 96 h LC50 = 158 mg/l

Aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 48 h EC50 = 249 mg/l

Algae:

Practically nontoxic. Desmodesmus subspicatus (green algae) 72 h EC50 (Growth inhibition) > 400 mg/l

Microorganisms:

Respiration inhibition / Activated sludge 3 h EC50 = 102.1 mg/l (similar material)

Chronic toxicity to fish:

Danio rerio (zebra fish) 34 d NOEC = 18 mg/l

Chronic toxicity to aquatic invertebrates:

Daphnia magna (Water flea) 21 d NOEC = 1.7 mg/l (data for a similar material)

Chronic toxicity to aquatic plants:

Desmodesmus subspicatus (green algae) 72 h EC10 = 80 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): not regulated

Special Shipping Information: Bulk Shipments: NA1993, Combustible liquid, n.o.s.(Dimethyl Sulfoxide),

Combustible liquid, PGIII.

International Maritime Dangerous Goods Code (IMDG): not regulated

15. REGULATORY INFORMATION

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Chemical Inventory Status

US. Toxic Substances Control Act TSCA FOR RESEARCH AND DEVELOPMENT

USE ONLY BY TECHNICALLY QUALIFIED INDIVIDUALS UNDER SECTION 5(h)(3) OF THE TOXIC SUBSTANCES CONTROL ACT.

Canadian Domestic Substances List (DSL)

DSL

This product contains one or several

components that are not on the Canadian

DSL nor NDSL lists.

China. Inventory of Existing Chemical Substances in IECSC (CN) Does not conform

China (IECSC)

Korea. Korean Existing Chemicals Inventory (KECI) KECI (KR) Does not conform

Philippines Inventory of Chemicals and Chemical PICCS (PH) Does not conform

Substances (PICCS)

Australia Inventory of Chemical Substances (AICS) AICS Does not conform

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

Substances Inventory

Japan. ISHL - Inventory of Chemical Substances ISHL (JP) Does not conform

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):

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

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New Jersey Right to Know

Chemical nameCAS-No.Methane, sulfinylbis-67-68-5

New Jersey Right to Know - Special Health Hazard Substance(s)

Chemical nameCAS-No.Methane, sulfinylbis-67-68-5

Pennsylvania Right to Know

Chemical nameCAS-No.Methane, sulfinylbis-67-68-5

Proprietary modified urea Proprietary

Stabilizer Proprietary

Benzene, 2,4-diisocyanato-1-methyl- 584-84-9

Methane, thiobis- 75-18-3

Pennsylvania Right to Know - Environmentally Hazardous Substance(s)

<u>CAS-No.</u>

Benzene, 2,4-diisocyanato-1-methyl- 584-84-9 Methane, thiobis- 75-18-3

Pennsylvania Right to Know - Special Hazardous Substance(s)

<u>Chemical name</u> <u>CAS-No.</u> Benzene, 2,4-diisocyanato-1-methyl- 584-84-9

California Prop. 65

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

Chemical nameCAS-No.Benzene, 2,4-diisocyanato-1-methyl-584-84-9

16. OTHER INFORMATION



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

H227 Combustible liquid.

H303 May be harmful if swallowed.

H315 Causes skin irritation.

H320 Causes eye irritation.

H413 May cause long lasting harmful effects to aquatic life.

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:
 200001695

 Date of Revision:
 12/17/2018

 Date Printed:
 12/17/2018

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 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.

TSCA R&D Exemption material

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One or more of the chemicals we are shipping you are not on the Toxic Substance Control Act (TSCA) Inventory list and are being sent to you as a research and development (R&D) chemicals. In order to be exempt from Premanufacturing Notification (PMN) requirements, the EPA requires that these chemicals be used solely for R&D and that all research is supervised by a "technically qualified individual" as defined in 40 C.F.R. 720.3(ee) (see below).

The chemical, physical, and toxicological properties of these chemicals may not have been fully investigated. Use due caution in the handling of this material and follow appropriate good industrial hygiene and safety precautions to control exposure. Consult the enclosed (attached) Safety Data Sheet (SDS) for additional information.

Because the conditions of handling and use are beyond our control, we make no guarantee of results and assume no liability for injuries, damages, or penalties resulting from the use whether or not our suggestions are followed. Such recommendations are not to be taken as a license to operate under or to infringe any patent.

40 C.F.R. 720.3(ee): Technically qualified individual means a person or persons (1) who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the chemical substance which is used under his or her supervision, (2) who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance required within the scope of conducting a research and developmental activity.

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