



SAFETY DATA SHEET

GALORYL® ATH F-AC

1. PRODUCT AND COMPANY IDENTIFICATION

Company

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

ArrMaz

Customer Service Telephone Number: (800) 993-7884
(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: GALORYL® ATH F-AC
Synonyms: Not available
Molecular formula: Not available
Chemical family: Anionic
Product use: Prilling Aid

SECTION 2: HAZARDS IDENTIFICATION

Emergency Overview

Color: Light Brown
Physical state: liquid
Odor: mild

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

Serious eye damage, Category 1, H318
Specific target organ toxicity - repeated exposure, Category 2, H373
Acute aquatic toxicity, Category 1, H400
Chronic aquatic toxicity, Category 3, H412

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

GHS-Labeling

Hazard pictograms:



Signal word:

Danger

Hazard statements:

H318 : Causes serious eye damage.

H373 : May cause damage to organs through prolonged or repeated exposure.

H400 : Very toxic to aquatic life.

H412 : Harmful to aquatic life with long lasting effects.

Supplemental Hazard Statements:

Specific target organ toxicity - repeated exposure:
gastrointestinal tract, immune system, liver.

Precautionary statements:

Prevention:

P260 : Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

P273 : Avoid release to the environment.

P280 : Wear eye protection and face protection.

Response:

P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 : Immediately call a POISON CENTER or doctor.

P391 : Collect spillage.

Disposal:

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

Supplemental information:

Potential Health Effects:

If swallowed, may cause severe irritation and injury to the mouth, throat and digestive tract.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Distillates (petroleum), solvent-refined heavy naphthenic	64741-96-4	>= 30 - < 60 %	Not classified
Paraffin oils (petroleum), catalytic dewaxed light	64742-71-8	>= 30 - < 60 %	H304
Amine	Proprietary*	>= 5 - < 10 %	H315, H318, H373, H304, H400, H411

*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.

SECTION 4: FIRST AID MEASURES

4.1. Description of necessary first-aid measures:

Inhalation:

If inhaled, remove victim to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

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:

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately.

Ingestion:

If swallowed, DO NOT induce vomiting. Get medical attention. If victim is fully conscious, give a cupful of water. Never give anything by mouth to an unconscious person.

GALORYL® ATH F-AC**4.2. Most important symptoms and effects, both 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 any immediate medical attention and special treatment needed:

Unless otherwise noted in Notes to Physician, no specific treatment noted; treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES**Extinguishing media (suitable):**

Water spray, Carbon dioxide (CO₂), Foam, Dry chemical

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 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
Hazardous organic compounds

SECTION 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. Avoid generation of vapors. Contain and collect spillage with non-combustible absorbent material such as clean sand, earth, diatomaceous earth or non-acidic clay and place into suitable properly labeled containers for prompt disposal. 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.



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SECTION 7: HANDLING AND STORAGE

Handling

General information on handling:

- Do not breathe vapor or mist.
- Do not taste or swallow.
- Do not get in eyes, on skin, or on clothing.
- Keep container tightly closed.
- Use only with adequate ventilation.
- Wash thoroughly after handling.
- Emptied container retains vapor and product residue.
- Observe all labeled safeguards until container is cleaned, reconditioned or destroyed.

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.

Storage incompatibility – General:

- Store separate from:
Strong oxidizing agents

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Distillates (petroleum), solvent-refined heavy naphthenic (64741-96-4)

US. ACGIH Threshold Limit Values

Form:	Inhalable fraction.
Time weighted average	5 mg/m3
Remarks:	Included in the regulation but with no data values. See regulation for further details.
Remarks:	Exposure by all routes should be carefully controlled to levels as low as possible.

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

Form:	Mist
PEL:	5 mg/m3

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

PEL:	500 ppm (2,000 mg/m3)
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**GALORYL® ATH F-AC****Paraffin oils (petroleum), catalytic dewaxed light (64742-71-8)**

US. ACGIH Threshold Limit Values

Form:	Inhalable fraction.
Time weighted average	5 mg/m ³

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

Form:	Mist
PEL:	5 mg/m ³

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.

Respiratory protection:

Do not breathe vapor or mist. 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:

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Where there is potential for eye contact, wear a face shield, chemical goggles, and have eye flushing equipment immediately available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Color:	Light Brown
Physical state:	liquid
Odor:	mild
Odor threshold:	No data available.
Flash point	No data available
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:	10.01 - 10.6 lb/gal
Specific Gravity (Relative density):	1.2 - 1.27 Water=1 (liquid)
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:	No data available.
Viscosity, kinematic:	> 20.5 mm ² /s 104 °F (40 °C)
Viscosity, dynamic:	No data available.
Oil/water partition	No data available.

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coefficient:

Thermal decomposition: No data available.

Flammability: See GHS Classification in Section 2 if applicable

SECTION 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:

Strong oxidizing agents

Conditions / hazards to avoid:

See HANDLING AND STORAGE section of this MSDS for specified conditions. See Hazardous Decomposition Products below.

Hazardous decomposition products:

Thermal decomposition giving flammable and toxic products :

Carbon oxides

Hazardous organic compounds

SECTION 11: TOXICOLOGICAL INFORMATION

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

Data for GALORYL® ATH F-AC**Acute toxicity****Inhalation:**

Practically nontoxic. 4 h Acute toxicity estimate > 10 mg/l. (dust/mist)

Data for Distillates (petroleum), solvent-refined heavy naphthenic (64741-96-4)**Acute toxicity****Oral:**

Practically nontoxic. (rat) LD50 > 5,000 mg/kg.

Dermal:

Practically nontoxic. (rabbit) LD50 > 5,000 mg/kg.

Inhalation:

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May be harmful if inhaled. (rat) 4 h LC50 = 5.53 mg/l. (dust/mist)

Skin Irritation:

Practically non-irritating. (rabbit) (24 h) (occluded exposure)

Eye Irritation:

Causes mild eye irritation. (rabbit)

Skin Sensitization:

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

Repeated dose toxicity

Repeated dermal administration to rabbit / No adverse systemic effects reported.

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

Genotoxicity

Assessment in Vitro:

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

Genotoxicity

Assessment in Vivo:

No genetic changes were observed in a laboratory test using: mouse

Developmental toxicity

Exposure during pregnancy. Dermal No birth defects were observed.

Other information

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

Human experience

Skin contact:

No skin allergy was observed..

Data for Paraffin oils (petroleum), catalytic dewaxed light (64742-71-8)

Acute toxicity

Oral:

No deaths occurred. (rat) LD0 > 5,000 mg/kg.

Dermal:

No deaths occurred. (rabbit) LD0 > 5,000 mg/kg. (occluded exposure)

Inhalation:

No deaths occurred. (rat) 4 h LC0 > 5.5 mg/l. (dust/mist)

Skin Irritation:

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Not irritating. (rabbit) (24 h) (occluded exposure)

Eye Irritation:

Not irritating. (rabbit)

Skin Sensitization:

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

Repeated dose toxicity

Subchronic oral administration to rat / affected organ(s): testes / signs: changes in blood cell counts, changes in organ weights, changes in body weight

Repeated dermal administration to rabbit / affected organ(s): testes / signs: skin irritation, changes in body weight, changes in organ weights / (occluded exposure)

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

Carcinogenicity

Chronic dermal administration to mice / No increase in tumor incidence was reported.

Genotoxicity

Assessment in Vitro:

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

Genotoxicity

Assessment in Vivo:

No genetic changes were observed in laboratory tests using: mice

Developmental toxicity

Exposure during pregnancy. Dermal (rat) / Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

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

Reproductive effects

Reproductive/Developmental Effects Screening Assay. Oral (rat) / No toxicity to reproduction. / (No birth defects were observed.)

Other information

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

Human experience

Skin contact:

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

Data for Amine (Proprietary)

Acute toxicity

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Oral:

May be harmful if swallowed. (rat) LD50 > 2,000 mg/kg.

Dermal:

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

Skin Irritation:

Causes skin irritation. (rabbit) (4 h)

Eye Irritation:

Causes serious eye damage. (rabbit)

Skin Sensitization:

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

Repeated dose toxicity

Repeated oral administration to rat / affected organ(s): Gastrointestinal tract, immune system, liver / signs: changes in organ structure or function

Repeated dermal administration to rat / affected organ(s): skin / signs: Local irritation

Specific target organ toxicity - repeated exposure:

May cause damage to organs through prolonged or repeated exposure. (Gastrointestinal tract, immune system, liver)

Genotoxicity

Assessment in Vitro:

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

Genotoxicity

Assessment in Vivo:

No genetic changes were observed in laboratory tests using: mice

Developmental toxicity

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

Reproductive effects

Reproductive/Developmental Effects Screening Assay. Oral (rat) / Effects on fertility at doses that produce effects in mothers

Other information

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

SECTION 12: ECOLOGICAL INFORMATION

Chemical Fate and Pathway

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

GALORYL® ATH F-AC**Data for Distillates (petroleum), solvent-refined heavy naphthenic (64741-96-4)****Biodegradation:**

Not readily biodegradable. (28 d) biodegradation 31 %

Octanol Water Partition Coefficient:

log Pow: = 1.99 - 18.02(Method: calculated)

Data for Paraffin oils (petroleum), catalytic dewaxed light (64742-71-8)**Biodegradation:**

Not readily biodegradable. (28 d) biodegradation 31.13 %

Octanol Water Partition Coefficient:

log Pow: 1.99 - 18.02(Method: calculated)

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

Readily biodegradable. (28 d) biodegradation > 60 %

Additional Information:

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

Ecotoxicology

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

Data for Distillates (petroleum), solvent-refined heavy naphthenic (64741-96-4)

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. Pimephales promelas (fathead minnow) LL50 > 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 > 100 mg/l (Nominal concentration, Water accommodated fraction was tested.)

Algae:

No effect up to the limit of solubility. Pseudokirchneriella subcapitata 72 h ErC50 > 100 mg/l (Nominal concentration, Water accommodated fraction was tested.)

Chronic toxicity to aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 21 d NOELR = 10 mg/l (Water accommodated fraction was tested.)

Chronic toxicity to aquatic plants:

No effect up to the limit of solubility. Pseudokirchneriella subcapitata (microalgae) 72 h NOEC r > 100 mg/l

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(Nominal concentration, Water accommodated fraction was tested.)

Data for Paraffin oils (petroleum), catalytic dewaxed light (64742-71-8)

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

Aquatic toxicity data:

Practically nontoxic. Pimephales promelas (fathead minnow) 96 h LL50 > 100 mg/l

Aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 48 h EL50 > 10,000 mg/l (Nominal concentration, Water accommodated fraction was tested.)

Practically nontoxic. Gammarus fasciatus (freshwater shrimp) 96 h LL50 > 10,000 mg/l (Nominal concentration, Water accommodated fraction was tested.)

Algae:

Practically nontoxic. Pseudokirchneriella subcapitata (algae) 72 h NOEC > 100 mg/l (Nominal concentration, Water accommodated fraction was tested.)

Chronic toxicity to aquatic invertebrates:

Practically nontoxic. semi-static test / Daphnia magna (Water flea) 21 d NOELR = 10 mg/l

Data for Amine (Proprietary)

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

Aquatic toxicity data:

Very toxic. Pimephales promelas (fathead minnow) 96 h LC50 = 0.06 mg/l

Aquatic invertebrates:

Very toxic. Daphnia magna (Water flea) 48 h EC50 = 0.98 mg/l

Algae:

Very toxic. Desmodesmus subspicatus (green algae) 72 h EC50 = 0.46 mg/l

Microorganisms:

Respiration inhibition / Activated sludge 3 h EC50 = 222.5 mg/l

Chronic toxicity to aquatic invertebrates:

Toxic. Reproduction Test / Daphnia magna (Water flea) 21 d NOEC = 0.013 mg/l

Chronic toxicity to aquatic plants:

Toxic. Desmodesmus subspicatus (green algae) 72 d NOEC = 0.015 mg/l

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SECTION 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.

SECTION 14: TRANSPORT INFORMATION

US Department of Transportation (DOT): not regulated

International Maritime Dangerous Goods Code (IMDG): not regulated

SECTION 15: REGULATORY INFORMATION

Chemical Inventory Status

US. Toxic Substances Control Act	TSCA	The components of this product are all on the Active 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)	All components of this product are listed or exempted
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Not all components of this product are listed or exempted
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Not all components of this product are listed or exempted
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	All components of this product are listed or exempted
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	All components of this product are listed or exempted
Australian Inventory of Industrial Chemicals	AU AIICL	All components of this product are listed or exempted
Taiwan Chemical Substance Inventory (TCSI)	TCSI	All components of this product are listed or exempted



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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, Chronic 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):

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>
Distillates (petroleum), solvent-refined heavy naphthenic	64741-96-4
Paraffin oils (petroleum), catalytic dewaxed light	64742-71-8

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

<u>Chemical name</u>	<u>CAS-No.</u>
Distillates (petroleum), solvent-refined heavy naphthenic	64741-96-4
Paraffin oils (petroleum), catalytic dewaxed light	64742-71-8

Pennsylvania Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
Distillates (petroleum), solvent-refined heavy naphthenic	64741-96-4
Paraffin oils (petroleum), catalytic dewaxed light	64742-71-8
Amine	Proprietary



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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.

SECTION 16: OTHER INFORMATION**Full text of H-Statements referred to under sections 2 and 3.**

- H304 May be fatal if swallowed and enters airways.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H400 Very toxic to aquatic life.
- H411 Toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.

Latest Revision(s):

Reference number:	200022495
Date of Revision:	05/02/2022
Date Printed:	05/03/2022

GALORYL® is a registered trademark of ArrMaz Products 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.