

RILSAN® BESVO A FDA

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® BESVO A FDA

Synonyms: Not available
Molecular formula: (C11H23NO2)x
Chemical family: polyamide

Product use:Mouldings and Extrusion

SECTION 2: HAZARDS IDENTIFICATION

Emergency Overview

Color: translucent
Physical state: solid
Form: pellets
Odor: odourless

*Classification of the substance or mixture:

Not a hazardous substance or mixture.

GHS-Labelling

Supplemental Hazard Statements:

Processing may release vapors and/or fumes which cause eye, skin and respiratory tract irritation.

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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. (pellets/granules) This product may release fume and/or vapor of variable composition depending on processing time and temperature.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Undecanoic acid, 11-amino-, homopolymer	25587-80-8	<= 100 %	Not classified

^{**}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.

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.

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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

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:

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
Hydrogen cyanide (hydrocyanic acid)
(traces)

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. Ventilate the area. Sweep up and shovel into suitable properly labeled containers for prompt disposal. Possible fall hazard – floor may become slippery from leakage/spillage of product. 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:

Avoid breathing dust.

Avoid breathing processing fumes or vapors.

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.

Storage stability - Remarks:

Stable under normal conditions.

Storage incompatibility - General:

None known.

Temperature tolerance - Do not store above:

140 °F (60 °C)

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Particles Not Otherwise Specified / Nuisance Dust (Proprietary)

US. ACGIH Threshold Limit Values

Form: Respirable particles.

Time weighted average 3 mg/m3

Form: Inhalable particles.

Time weighted average 10 mg/m3

US. OSHA Table Z-3 (29 CFR 1910.1000)

Form: Respirable fraction.

Time weighted average 15millions of particles per cubic foot of air

US. OSHA Table Z-3 (29 CFR 1910.1000)

Form: Total dust

Time weighted average 50millions of particles per cubic foot of air

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US. OSHA Table Z-3 (29 CFR 1910.1000)

Form: Respirable fraction.

Time weighted average 5 mg/m3

US. OSHA Table Z-3 (29 CFR 1910.1000)

Form: Total dust Time weighted average 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.

Respiratory protection:

Avoid breathing dust. Avoid breathing processing fumes or vapors. 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.

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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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Color: translucent

Physical state: solid

Form: pellets

Odor: odourless

Odor threshold: No data available

Flash point Not applicable

Lower flammable limit

(LFL):

No data available

Upper flammable limit

(UFL):

No data available

pH: No data available

Density: 1.0 - 1.5 g/cm3

Specific Gravity (Relative

density):

1.0 - 1.5 Water=1 (liquid)

Boiling point/boiling

range:

No data available

Melting point/range: 347 - 374 °F (175 - 190 °C)

Freezing point: No data available

Evaporation rate: No data available

Solubility in water: negligible

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 if applicable

SECTION 10: STABILITY AND REACTIVITY

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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

SECTION 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:

Amine derivatives

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

Dermal:

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

Skin Irritation:

Not irritating. (In vitro)

Eye Irritation:

Not corrosive (Bovine cornea)

Skin Sensitization:

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

Repeated dose toxicity

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

Genotoxicity

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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.

SECTION 12: ECOLOGICAL INFORMATION

Chemical Fate and Pathway

No data are available.

Ecotoxicology

No data are available.

SECTION 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.

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)

Conforms to

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Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Conforms to
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Conforms to
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Conforms to
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	Conforms to
Australia Inventory of Chemical Substances (AICS)	AICS	Conforms to

United States - Federal Regulations

SARA Title III - Section 302 Extremely Hazardous Chemicals:

The components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.

SARA Title III - Section 311/312 Hazard Categories:

No SARA Hazards

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

No components are subject to the New Jersey Right to Know Act.

Pennsylvania Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
Undecanoic acid, 11-amino-, homopolymer	25587-80-8

Methanol 67-56-1

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Pennsylvania Right to Know - Environmentally Hazardous Substance(s)

<u>Chemical name</u> <u>CAS-No.</u>

Methanol 67-56-1

California Prop. 65

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

Chemical nameCAS-No.Methanol67-56-1

SECTION 16: OTHER INFORMATION

Latest Revision(s):

 Reference number:
 200006369

 Date of Revision:
 10/15/2021

 Date Printed:
 10/15/2021

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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.

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