

PEBAX® 4033 SA 01 MED**1. PRODUCT AND COMPANY IDENTIFICATION****Company**

Arkema Inc.
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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: PEBAX® 4033 SA 01 MED
Synonyms: Not available
Molecular formula: Not applicable
Chemical family: polyamide
Product use: Mouldings and Extrusion

2. HAZARDS IDENTIFICATION**Emergency Overview**

Color: colourless to slightly yellow
Physical state: solid
Form: pellets
Odor: none

***Classification of the substance or mixture:**
Not a hazardous substance or mixture.

GHS-Labeling**Supplemental Hazard Statements:**

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

Supplemental information:**Potential Health Effects:**

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

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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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Hexanedioic acid, polymer with azacyclotridecan-2-one and .alpha.-hydro-.omega.-hydroxypoly(oxy-1,4-butanediyl)	77402-38-1	99 - 100 %	Not classified

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

4. FIRST AID MEASURES

4.1. Description of necessary first-aid measures:

Inhalation:

If inhaled, remove victim to fresh air.

Skin:

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

Eyes:

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

Ingestion:

If swallowed, DO NOT induce vomiting. Get medical attention. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms/effects, acute and delayed:

For most important symptoms and effects (acute and delayed), see Section 2 (Hazard Statements and Supplemental Information) and Section 11 (Toxicology Information) of this SDS.

4.3. Indication of immediate medical attention and special treatment needed, if necessary:

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

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

Water spray, 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

Hydrogen cyanide (hydrocyanic acid)
(traces)

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. 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.

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)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Particles Not Otherwise Specified / Nuisance Dust (Proprietary)

US. ACGIH Threshold Limit Values

Form:	Inhalable particles.
Time weighted average	10 mg/m ³
Form:	Respirable particles.
Time weighted average	3 mg/m ³

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

Form:	Respirable fraction.
PEL:	5 mg/m ³

Form:	Total dust
PEL:	15 mg/m ³

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

Form:	Respirable fraction.
Time weighted average	15millions of particles per cubic foot of air

Form:	Total dust
Time weighted average	50millions of particles per cubic foot of air

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

Form:	Total dust
Time weighted average	15 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.

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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.

9. PHYSICAL AND CHEMICAL PROPERTIES
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Color:	colourless to slightly yellow
Physical state:	solid
Form:	pellets
Odor:	none
Odor threshold:	No data available
Flash point	No data available
Auto-ignition temperature:	698 - 842 °F (370 - 450 °C) (Method: Standard ASTM D 1929-77 (B))
Lower flammable limit (LFL):	Not applicable
Upper flammable limit (UFL):	Not applicable

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pH:	No data available
Density:	No data available
Specific Gravity (Relative density):	No data available
Bulk density:	550 - 650 kg/m ³
Vapor pressure:	No data available
Vapor density:	No data available
Boiling point/boiling range:	Not applicable
Melting point/range:	320 °F (160 °C)
Freezing point:	Not applicable
Evaporation rate:	No data available
Solubility in water:	68 °F (20 °C) insoluble
Solubility in other solvents: [qualitative and quantitative]	Soluble in: Phenols Metacresol Benzyl alcohol (when hot) Formic acid (concentrate), Sulphuric acid (concentrate) partly soluble Methylene chloride (dichloromethane)
Viscosity, dynamic:	No data available
Oil/water partition coefficient:	No data available
Thermal decomposition	572 - 662 °F (300 - 350 °C)
Net calorific value	34.000 - 37.000 kJ/kg (Method: Standard : NF M 03 0005)
Flammability:	See GHS Classification in Section 2

10. STABILITY AND REACTIVITY**Stability:**

The product is stable under normal handling and storage conditions.

Hazardous reactions:

Hazardous polymerization does not occur.

Materials to avoid:

None known.

Conditions / hazards to avoid:

Avoid storing in moist and warm conditions. (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:

Ammonia

Amino derivatives

Hazardous organic compounds

Carbon oxides

Hydrogen cyanide (hydrocyanic acid)

(traces)

11. TOXICOLOGICAL INFORMATION

Data on this material and/or a similar material are summarized below.

Data for PEBAX® 4033 SA 01 MED**Acute toxicity****Oral:**

Practically nontoxic. (rat) LD0 > 4,000 mg/kg.

Skin Irritation:

Not irritating. (rabbit) Irritation Index: 0/8. (4 h) (similar material)

Eye Irritation:

Causes mild eye irritation. (rabbit) Irritation Index: 5 /110. (similar material)

Skin Sensitization:

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

Genotoxicity**Assessment in Vitro:**

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

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Assessment in Vivo:

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

12. ECOLOGICAL INFORMATION

Chemical Fate and Pathway

No data are available.

Ecotoxicology

No data are available.

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.

14. TRANSPORT INFORMATION

US Department of Transportation (DOT): not regulated

International Maritime Dangerous Goods Code (IMDG): not regulated

15. REGULATORY INFORMATION

Chemical Inventory Status

EU. EINECS	EINECS	Conforms to
United States TSCA Inventory	TSCA	The components of this product are all on the TSCA Inventory.
Canadian Domestic Substances List (DSL)	DSL	All components of this product are on the Canadian DSL
China. Inventory of Existing Chemical Substances in China (IECSC)	IECSC (CN)	Conforms to
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Conforms to
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Conforms to

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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>
Hexanedioic acid, polymer with azacyclotridecan-2-one and .alpha.-hydro-.omega.-hydroxypoly(oxy-1,4-butanediyl)	77402-38-1

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

Latest Revision(s):

Reference number:	00000043905
Date of Revision:	11/10/2016
Date Printed:	11/16/2016

PEBAX® 4033 SA 01 MED

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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.