

PEBAX® 7433 SA 01 MED

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: PEBAX® 7433 SA 01 MED

Synonyms: Not available

Molecular formula: (C12H23NO.C6H10O4.(C4H8O)nH2O)x

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-Labelling

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 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

Product code: A07534 Version 2.1 Issued on: 10/17/2015 Page: 1 / 10



PEBAX® 7433 SA 01 MED

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 .alphahydro-omegahydroxypoly(oxy-1,4-butanediyl)	77402-38-1	<= 100 %	Not classified

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

4. 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.

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:

Product code: A07534 Version 2.1 Issued on: 10/17/2015 Page: 2 / 10



PEBAX® 7433 SA 01 MED

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)

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 recommended storage conditions.

Storage incompatibility - General:

None known.

Temperature tolerance - Do not store above:

140 °F (60 °C)

Product code: A07534 Version 2.1 Issued on: 10/17/2015 Page: 3 / 10



PEBAX® 7433 SA 01 MED

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/m3

Form: Respirable particles.

Time weighted average 3 mg/m3

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

Form: Respirable fraction.

PEL: 5 mg/m3

Form: Total dust PEL: 15 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

Form: Total dust

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

Form: Respirable fraction.

Time weighted average 5 mg/m3

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.

Product code: A07534 Version 2.1 Issued on: 10/17/2015 Page: 4 / 10



PEBAX® 7433 SA 01 MED

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

Color: colourless to slightly yellow

Physical state: solid

Form: pellets

Odor: none

Odor threshold: No data available

Flash point Not applicable

Auto-ignition 698 - 842 °F (370 - 450 °C)

temperature:

Lower flammable limit

(LFL):

No data available

Upper flammable limit

(UFL):

No data available

pH: Not applicable

Density: No data available

Bulk density: 550 - 650 kg/m3 68 °F (20 °C)



PEBAX® 7433 SA 01 MED

Vapor pressure: Not applicable

Vapor density: Not applicable

Boiling point/boiling

range:

No data available

Melting point/range: 347 °F (175 °C)

Freezing point: No data available

Evaporation rate: No data available

Solubility in water: 68 °F (20 °C) insoluble

Solubility in other solvents: [qualitative and

quantative]

Soluble in:

Phenol

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)

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.

Product code: A07534 Version 2.1 Issued on: 10/17/2015 Page: 6 / 10



PEBAX® 7433 SA 01 MED

Hazardous decomposition products:

Thermal decomposition giving toxic, flammable, and / or corrosive products: Carbon oxides
Ammonia
Amino derivatives
Hydrogen cyanide (hydrocyanic acid)
(traces)
Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

Data for PEBAX® 7433 SA 01 MED

Acute toxicity

Oral:

No deaths occurred. (Rat) LD0 > 4,000 mg/kg.

Skin Irritation:

Not irritating. (Rabbit) Irritation Index: 0/8. (4 h)

Eye Irritation:

Causes mild eye irritation. (Rabbit)

Skin Sensitization:

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

Genotoxicity

Assessment in Vitro:

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

Assessment in Vivo:

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

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.

12. ECOLOGICAL INFORMATION

Chemical Fate and Pathway

No data are available.

Ecotoxicology

No data are available.

Product code: A07534 Version 2.1 Issued on: 10/17/2015 Page: 7 / 10



PEBAX® 7433 SA 01 MED

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
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

Product code: A07534 Version 2.1 Issued on: 10/17/2015 Page: 8 / 10



PEBAX® 7433 SA 01 MED

<u>United States – Federal Regulations</u>

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>

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

CAS-No.
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:
 000000075611

 Date of Revision:
 10/17/2015

 Date Printed:
 11/29/2016

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Product code: A07534 Version 2.1 Issued on: 10/17/2015 Page: 9 / 10



PEBAX® 7433 SA 01 MED

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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.

Product code: A07534 Version 2.1 Issued on: 10/17/2015 Page: 10 / 10