

1. PRODUCT AND COMPANY IDENTIFICATION

<u>Company</u>	
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
Medical:	(24 hrs., 7 days a week) Rocky Mountain Poison Center: (866) 767-5089 (24 hrs., 7 days a week)
Product Information	
Product name: Synonyms: Molecular formula: Chemical family:	PEBAX® 5513 SA 01 Not available Not applicable polyamide

SECTION 2: HAZARDS IDENTIFICATION

Emergency Overview

Product use:

Color:colourless to slightly yellowPhysical state:solidForm:pelletsOdor: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.

Mouldings and Extrusion

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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 or residual monomer: Irritating to eyes, respiratory system and skin. Data for residual monomer:

Prolonged or repeated exposure may cause: local irritation, drying of skin, dermatitis, nosebleeds, drowsiness, headache, nausea, weakness, convulsions, loss of consciousness, (severity of effects depends on extent of exposure).

Medical conditions aggravated by overexposure:

Respiratory disease or diminished respiratory capacity. Skin disorders. (Data for residual monomer that may be released during processing)

Other:

Handle in accordance with good industrial hygiene and safety practice. 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**
Hexanedioic acid, polymer with hexahydro-2H-azepin-2-one and .alphahydroomega hydroxypoly(oxy-1,4-butanediyl)	66139-31-9	98 %	Not classified
2H-Azepin-2-one, hexahydro-	105-60-2	2 %	H302, H315, H320, H335

**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.

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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 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)

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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.

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 recommended storage 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:

2H-Azepin-2-one, hexahydro- (105-60-2)

US. ACGIH Threshold Limit Values

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Form: Time weighted average

Inhalable fraction and vapor. 5 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

Color:	colourless to slightly yellow
Physical state:	solid
Form:	pellets
Odor:	odourless
Odor threshold:	No data available
Flash point	Not applicable

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Auto-ignition temperature:	698 - 842 °F (370 - 450 °C) (Method: Standard ASTM D 1929-77 (B))
Lower flammable limit (LFL):	No data available
Upper flammable limit (UFL):	No data available
pH:	Not applicable
Density:	1.09 g/cm3
Specific Gravity (Relative density):	1.09 Water=1 (liquid)
Bulk density:	550 - 650 kg/m3
Boiling point/boiling range:	Not applicable
Melting point/range:	383 °F (195 °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:
	Phenols
	Metacresol
	Benzyl alcohol (when hot)
	Formic acid (concentrate), Sulphuric acid (concentrate)
	Methylene chloride (dichloromethane) partly soluble
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 if applicable

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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:

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: Carbon oxides Ammonia Amino derivatives 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 PEBAX® 5513 SA 01

Acute toxicity

Oral: Practically nontoxic. Acute toxicity estimate > 5,000 mg/kg.

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

Data for 2H-Azepin-2-one, hexahydro- (105-60-2)

Acute toxicity

Oral: Harmful if swallowed. (rat) LD50 = 1,475 mg/kg.

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

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Inhalation: Practically nontoxic. (rat) 4 h LC50 = 8.16 mg/l. (dust/mist)

Specific target organ toxicity - single exposure:

May cause respiratory irritation.

Eye Irritation: Causes eye irritation. (rabbit)

Skin Sensitization:

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

Repeated dose toxicity

Subchronic inhalation administration to rat / affected organ(s): upper respiratory tract / signs: changes in organ structure or function / No significant impairment of function. (dust)

Subchronic dietary administration to rat / affected organ(s): kidney, liver, testes / signs: changes in organ weights, hyaline droplet nephropathy / (not considered relevant in humans)

Repeated exposure dietary administration to Dog / No adverse effects reported.

Carcinogenicity

Chronic dietary administration to rat and mouse / No increase in tumor incidence was reported. Classified by the International Agency for Research on Cancer as: Group 4: Probably not carcinogenic to humans.

Genotoxicity

Assessment in Vitro:

No genetic changes were observed in laboratory tests using: bacteria

Both positive and negative responses for genetic changes were observed in laboratory tests using: animal cells, human cells

Genotoxicity

Assessment in Vivo:

No genetic changes were observed in laboratory tests using: rats, mice

Developmental toxicity

Exposure during pregnancy. oral (rat and rabbit) / No birth defects were observed. (levels produced toxic effects in the mothers and offspring)

Reproductive effects

Three-generation study. oral (rat) / No toxicity to reproduction.

Human experience

General:

A workplace incident reported fever, nausea, vomiting, seizures, dermatitis. No effects on lung function or blood parameters. (based on a report of occupational exposure to workers)

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Human experience

Inhalation:

Respiratory tract: Discomfort, nosebleeds, dry/splitting nose, dry/splitting lips, inflammation of the membranes of the respiratory tract. (vapor)

Human experience

Skin contact:

Skin allergy was observed. (based on reports of occupational exposure to workers) Isolated case reports after exposure to a mixture containing this substance.

skin irritation, contact dermatitis. (based on reports of occupational exposure to workers) (repeated or prolonged exposure)

Human experience

Eye contact: Eyes: Discomfort. (vapor)

SECTION 12: ECOLOGICAL INFORMATION

Chemical Fate and Pathway

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

Data for 2H-Azepin-2-one, hexahydro- (105-60-2)

Biodegradation:

Readily biodegradable. (14 d) biodegradation 82 %

Octanol Water Partition Coefficient:

log Pow: = 0.12, at 77 °F (25 °C)

Ecotoxicology

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

Data for 2H-Azepin-2-one, hexahydro- (105-60-2)

Aquatic toxicity data:

Practically nontoxic. Oryzias latipes 96 h LC50 > 100 mg/l

Aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 48 h EC50 > 1,000 mg/l

Algae:

Practically nontoxic. Pseudokirchneriella subcapitata (green algae) 72 h EC50 > 1,000 mg/l

Microorganisms:

Pseudomonas putida 17 h EC50 = 4,240 mg/l

Chronic toxicity to aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 21 d NOEC (reproduction) = 100 mg/l

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Chronic toxicity to aquatic plants:

Practically nontoxic. Pseudokirchneriella subcapitata 72 h NOEC = 1000 mg/l

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

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	This product contains one or several components listed in the Canadian NDSL list. All other components are on the DSL list.
China. Inventory of Existing Chemical Substances in China (IECSC)	IECSC (CN)	Does not conform
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	All components of this product are listed or exempted
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	All components of this product are listed or exempted
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Does not conform
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	The mixture contains a polymer. All the monomers for this polymer & other substances are listed on the inventory.

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SAFETY DATA SHEET

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Australian Inventory of Industrial Chemicals	AU AIICL	Not all components of this product are listed or exempted
Taiwan Chemical Substance Inventory (TCSI)	TCSI	Not all components of this product are listed or exempted

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

Chemical name	CAS-No.
2H-Azepin-2-one, hexahydro-	105-60-2

Pennsylvania Right to Know

Chemical name	CAS-No.
Hexanedioic acid, polymer with hexahydro-2H-azepin-2-	66139-31-9
one and .alphahydroomegahydroxypoly(oxy-1,4-	
butanediyl)	

2H-Azepin-2-one, hexahydro-

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

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

H302 Harmful if swallowed.

- H315 Causes skin irritation.
- H320 Causes eye irritation.
- H335 May cause respiratory irritation.

Latest Revision(s):

Reference number:	200006931
Date of Revision:	03/08/2022
Date Printed:	03/08/2022

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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.

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