SAFETY DATA SHEETS

This SDS packet was issued with item:

078940380

N/A

SAFETY DATA SHEET

ALKEM

1. IDENTIFICATION

Material	:	Azathioprine Tablets USP 25/50/75/100 mg
Recommended Use	:	Rx Pharmaceutical for human use
Manufacturer	:	Alkem Laboratories Ltd. Mumbai - 400013, INDIA.
Distributor	:	Ascend Laboratories, LLC Parsippany, NJ 07054
Contact Phone Number	:	001-201-476-1977

2. HAZARD(S) IDENTIFICATION

Form	Tablets
Color	Yellow to off white
Health hazard	Carcinogenicity Category 2A
Hazard symbol	None
Hazard Statements:	This is pharmaceutical product designed to be prescribed by a license healthcare professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
Signal word	Warning
Precautionary Statements	
Prevention	Observe good industrial hygiene practice.
Response	Wash hand after handling.
Storage	Protect from light, protect from moisture.
OSHA define hazard	Not Classified
Other Hazards	Product is in tablet form, but contains substances that are combustible dusts. If these substances in their powder form are allowed to accumulate, dispersed in sufficient quantities in air, and in the presence of an ignition source may cause a dust explosion

3. COMPOSITION / INFORMATION ON INGREDIENTS

Active Ingredient	**CAS No.**	**Strengths**
Azathioprine USP	446-86-6	25 mg, 50 mg, 75mg and 100 mg

Inactive Ingredient	**CAS No.**
Lactose Monohydrate	10039-26-6
Maize Starch	9005-25-8

Croscarmellose Sodium	74811-65-7
Povidone K30	9003-39-8
Magnesium Stearate	557-04-0

4. FIRST-AID MEASURE

Eye contact - The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 60 minutes. If easy to do, remove contact lenses. Get medical attention.

Skin contact - Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Inhalation - The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Ingestion - Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention (show the label where possible).

Most Important Symptoms and Effects, both Acute and Delayed

Eye contact - Causes serious eye damage

Skin contact - Causes skin irritation

Inhalation - May cause irritation to the respiratory tract.

Ingestion - Harmful if swallowed. Potent pharmaceutical- ingestion may be harmful or have adverse effects

Chronic symptoms - May cause genetic defects. May cause cancer. May damage fertility or the unborn child. May cause harm to breast-fed children

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: - If exposed or concerned, get medical advice and attention.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media – Not flammable. Use extinguishing media appropriate for surrounding fire.

Explosion hazard – Product is in pill form, but contains substances that are combustible dusts. If these substances in their powder form are allowed to accumulate, dispersed in sufficient quantities in air, and in the presence of an ignition source, it may cause a dust explosion.

Hazardous decomposition products in case of fire	–	Carbon oxides (CO, CO2). Nitrogen oxides. Sulphur oxides. Sulphur compounds
Special method of fire-fighting	–	Use water spray or fog for cooling exposed containers. Avoid raising dust, Do not enter fire area without proper protective equipment, including respiratory protection.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions Protective equipment and emergency procedure	–	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Precautions	–	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:	–	For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labelled, sealed container for proper disposal. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Vacuum must be fitted with HEPA filter to prevent release of particulates during clean-up.
Additional Consideration for Large Spills:	–	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Storage conditions	–	Store at 20°C to 25°C (68° to 77°F), (see USP Controlled Room Temperature) in a dry place and protect from light. Dispense in tight, light-resistant container as defined in the USP

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ocupational exposure limit	-	Refer to available public information for specific member state Occupational Exposure Limits.
Control parameter	-	No additional information available

Exposure control

Hands:	-	Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.
Eyes	-	In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended
Skin	-	In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.
Respiratory protection	-	When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form: Yellow to off white uncoated tablet

Sr. No.	Strength	Description	Packs	NDC No
1	25mg	Round, yellow to off white uncoated tablet, scored, debossed with "AZA" on upper side of score line and "25" on lower side of the score line and plain on the other side.	Bottle of 100 tablets	67877-492-01
			Bottle of 500 tablets	67877-492-05
			Bottle of 1000 tablets	67877-492-10
			Carton of 14 (1 x 14) Unit-dose tablets.	67877-492-14
			Carton of 100 (10 x 10) Unit-dose tablets.	67877-492-38
2	50mg	Overlapping circular-shaped, yellow to off white uncoated tablet, scored, debossed with "AZA" on left side of score line and "50" on right side of the score line and plain on the other side.	Bottle of 100 tablets	67877-493-01
			Bottle of 500 tablets	67877-493-05
			Bottle of 1000 tablets	67877-493-10
			Carton of 100 (10 x 10) Unit-dose tablets.	67877-493-38
3	75mg	Capsule shaped, yellow to off white uncoated tablet, scored, debossed with "AZA" on left side of score line and "75" on right side of the score line and plain on the other side.	Bottle of 100 tablets	67877-494-01
			Bottle of 500 tablets	67877-494-05
			Bottle of 1000 tablets	67877-494-10
			Carton of 100 (10 x 10) Unit-dose tablets.	67877-494-38
4	100mg	Capsule shaped, yellow to off white uncoated tablet, scored, debossed with "AZA" on left side of score line and "100" on right side of the score line and plain on the other side.	Bottle of 100 tablets	67877-495-01
			Bottle of 500 tablets	67877-495-05
			Bottle of 1000 tablets	67877-495-10
			Carton of 100 (10 x 10) Unit-dose tablets.	67877-495-38

10. STABILITY AND REACTIVITY

Stability	–	Stable under normal conditions of use
Conditions to avoid	–	Direct sunlight. Extremely high or low temperatures. Incompatible materials. Avoid creating or spreading dust
Incompatible materials	–	Strong oxidizers. Strong bases. Strong acids. Methyl and propyl parabens. Phenol. Moisture.
Hazardous decomposition products	–	Carbon oxides (CO, CO2). Nitrogen oxides. Sulphur oxides. Sulphur compounds.

11. TOXICOLOGICAL INFORMATION

General Information	-	The information included in this section describes the potential hazards of the individual ingredients
Short Term	-	May be harmful if swallowed. May cause eye irritation (based on components).

LD50 Data of active ingredient

Oral (Rat)	–	400 mg/kg bodyweight
Oral (Mouse)	–	1389 mg/kg bodyweight
Skin Corrosion/Irritation	–	Causes skin irritation
Respiratory or Skin Sensitization	–	Not classified
Germ Cell Mutagenicity	–	May cause genetic defects.
Carcinogenicity	–	May cause cancer
Specific Target Organ Toxicity (Repeated Exposure)	–	Not classified
Reproductive Toxicity	–	May damage fertility or the unborn child. May cause harm to breast-fed children.
Specific Target Organ Toxicity (Single Exposure)	–	May cause respiratory irritation.
Aspiration Hazard	–	Not classified

LD50 and LC50 Data of ingrdients

– Not available

12. ECOLOGICAL INFORMATION

Ecology - General: Not classified.

Persistence and degradability: No data available

Bioaccumulative potential: No data available

Bioaccumulative potential: No data available

Mobility in soil : No data available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods: - Dispose of waste material in accordance with all local, regional, national, and international regulations. Do not dispose of waste into sewer

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

In accordance with ADR / RID / IMDG / IATA / ADN

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

1. Azathioprine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA	Not Listed

16. OTHER INFORMATION

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections, which pertain to their particular conditions.

Alkem or Ascend shall not be held liable for any damage resulting from handling or from contact with the above product. Alkem or Ascend reserves the right to revise this SDS.

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.

Date of Preparation: 16/04/2020