Aleor Dermaceuticals Limited

Material Safety Data Sheet **Preparation on.: 28/01/2022**
MSDS/EHS/019 Rev 00

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Name of Product	Clobetasol Propionate Ointment USP, 0.05%
Identified Use	Clobetasol Propionate Ointment USP, 0.05% is super-high potency corticosteroid formulations indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

Manufactured At: -

Aleor Dermaceuticals Limited.
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2. HAZARDS IDENTIFICATION

Fire & Explosion: - The product is noncombustible although packaging material is combustible.
Health: - No data Available.
Environment: - No data Available.
Other Hazards: - None

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS No.	Percentage
Clobetasol Propionate	25122-46-7	Not Available.
Sorbitan Sequioleate NF	8007-43-0	
Propylene glycol USP	57-55-6	
White Petrolatum	8009-03-8	

4. FIRST AID MEASURES

Description of first aid measures

General advice - Consult a physician. Show this safety data sheet to the doctor in attendance.

Injection: - Never give anything by mouth to an unconscious person. Seek Medical attention.
Inhalation - Take victim to fresh air. Seek medical Attention.
In **case of skin contact -** Wash skin with plenty of water. If adverse skin effects occur discontinue use and seek medical attention. physician.
In case of eye contact - If eye contact occurs, flush immediately with copious amount of water for at least 15 minutes. If eye irritation persists, seek medical attention.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Dry Chemical Powder Fire extinguisher are recommended to extinguish the fire.

Advice for firefighters

Since toxic vapors might be develop from fires involving this product and associated packaging, self-contained breathing apparatus and full-protective suits are recommended for firefighters.

Further information: - No data available.

6. ACCIDENTAL RELEASE MEASURES

Small Spills: Wear goggles and gloves while wiping up with spill pads or sponge.
Large spills: Same as for small spill, but in addition use a self-contained breathing apparatus should be used to avoid inhalation.
Environmental Precautions: Do not let the product to enter drains. Discharge into the environment must be avoided.
Others: - Observe all federal, state and local regulations when disposing this product.

7. HANDLING AND STORAGE

Precautions for Safe Handling: No Special Personal Protective Equipment's is required which handling or applying of this product.
Conditions for Safe Storage, Including Any Incompatibilities: Store at 20° to 25°C **(**68**°** to 77°F); excursions permitted between 15° to 30°C (59° to 86°F} [see USP Controlled Room Temperature].
Any Incompatibilities: - No Data Available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Controls: - When used as directed, engineering controls for final product are not generally required.

Personal Protection Equipment.

Eye Protection: - Not needed during routine use. During bulk handling of this products safety googles are recommended if eye contact is possible.

Hand/ Skin Protection: -. Not needed during routine use. During bulk handling of this products and for situation in which prolonged skin contact is anticipated, to avoid contact with skin, nitrile hand gloves is recommended.

Respiratory Protection: A respirator is not required for routine conditions of use of this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Semi-Solid, Viscous Ointment.
Color	White to Off white homogeneous ointment.
Odor	Not data available.
pH	No data available.
Melting point/freezing point	No data available.
Boiling point	No data available.
Flash point	No data available.
Evaporation Rate	No data available.
Solubility (water)	No data available.
Explosive Properties	Not Explosive.
Viscosity	Between 5000 and 16000 mPa.s

Clobetasol Propionate Ointment USP, 0.05%	**NDC Code**
15 g Tube	62332-465-15
30 g Tube	62332-465-30
45 g Tube	62332-465-45
60 g Tube	62332-465-60

10. STABILITY AND REACTIVITY

Reactivity: The product is non-reactive under normal conditions of use, storage and transport.
- **Chemical Stability:** Stable under use and storage conditions as recommended.
- **Incompatible products**: No Data Available.
- **Incompatible materials:** No Data Available**.**

11. TOXICOLOGICAL INFORMATION

No Information available.

12. ECOLOGICAL INFORMATION

Toxicity – Do not discharge into sewer or waterways.
Persistence and degradability - No Data Available
Bio accumulative potential - No Data Available
Mobility in soil - No Data Available
Other adverse effects - No Data Available.

13. DISPOSAL CONSIDERATIONS

Product

As specific country, federal, state and local environmental regulations are varied and change frequently, we recommend that you contact your local department for Health Services for information on the correct disposal of this product.

14. TRANSPORT INFORMATION

International Air Transport Association (IATA/IACO): This product is Not regulated / Classified as Dangerous Goods, as per guideline of Transport of Dangerous Goods/IATA.

International Maritime Organization (IMO): This product is Not regulated/Classified as Dangerous Goods, as per guideline of Transport of Dangerous Goods.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

No data available.

Chemical Safety Assessment

No data available.

16. OTHER INFORMATION

Further information.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide for technically qualified personnel. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product Aleor Dermaceuticals Ltd. extends no warranties, makes no representations and assumes no responsibility as to the accuracy, completeness or suitability of this data for any third-party use & shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale. Refer Patient Information Leaflet for details. The information shall be revise if any changes is updated in drug products.