

MATERIAL SAFETY DATA SHEET



Product Name: ADAPALENE GEL USP, 0.3%

Revision Date: 12/16/2021

Version No.: 00

1. IDENTIFICATION

Product Name	ADAPALENE GEL USP, 0.3%
Manufacturer Name	Encube Ethicals Pvt. Ltd.
Address	Plot No.C-1, Madkaim Industrial Estate Madkaim, Post- Mardol, Ponda Goa – 403 404, India.
Chemical name	6-(3-(1-Adamantyl)-4-methoxyphenyl)-2-naphthoic acid
Recommended use	Indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

2. HAZARD(S) IDENTIFICATION

Hazards	This is a personal care or cosmetic product that is safe for consumers and other users under the intended and reasonably foreseeable use. Additional information on toxicology endpoints may be available from the supplier upon request.
Route of Entry	
Inhalation	No
Absorption	Yes
Ingestion	Yes
Potential Effect of Exposure	
Ingestion	If product is swallowed, may cause nausea, vomiting and/or diarrhoea.
Skin	May be irritating to the skin in some sensitive individuals.
Eyes	Moderate irritation may occur
Inhalation	This product is non-volatile; therefore, inhalation is unlikely

3. COMPOSITION / INFORMATION ON INGREDIENT

Common name / Chemical name	6-(3-(1-Adamantyl)-4-methoxyphenyl)-2-naphthoic acid
CAS No.	106685-40-9
Concentration	0.3%
Other Ingredients	Poloxamer 182, Edetate Disodium, Methyl Paraben Propylene Glycol Carbopol-980, Sodium Hydroxide, Hydrochloric Acid and Purified Water.

4. FIRST-AID MEASURES

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Inhalation	If respiratory irritation occurs, remove individual to fresh air
Skin contact	If redness, dryness or other signs of irritation occur wash the affected Area with warm water and soap. If irritation persists contact a Physician.
Eye contact	If the product is in the eyes, do not rub eyes. Flush with copious amount of lukewarm water for at least 15 minutes. Open and close eyelid to ensure thorough irrigation. If irritation persists contact a physician
Ingestion	Accidental ingestion of product may necessitate medical attention. In case of accidental ingestion dilute with fluids (water or milk) and treat Symptomatically. Do not induce vomiting. Never give anything by mouth to an unconscious person. Contact the nearest Poison Control Centre or local emergency number. Provide an estimate of the time and amount of the substance swallowed.
Most important symptoms/effects, acute and delayed	None known
Indication of immediate medical attention and special treatment needed	Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media	Foam, CO ₂ , dry chemical powder, water spray, sand/earth as applicable to surrounding fire conditions.
Specific hazards arising from the chemical	This product may be combustible if exposed to direct flame or if exposed temperatures for a prolonged period. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides).
Special protective equipment and precautions for fire-fighters	As in any fire, wear MSHA/NIOSH approved self-contained breathing apparatus (pressure-demand) and full protective gear as applicable to surrounding fire conditions.
Firefighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen

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6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures Floor may become slippery. Absorb spilled material with inert material such as sawdust, sand or earth. Cleaning may require use of steam, solvents or detergents

Methods and materials for containment and cleaning up Small Spills: Small spills of this product should be cleaned immediately by personnel wearing gowns and double latex or nitrile disposable gloves and eye protection. Wipe up spilled material carefully with poly pad or sponge.

Large Spills: Trained personnel following pre-planned procedures should handle non-incident releases. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of airborne mists being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Wipe up spilled gel, avoiding the generation of airborne mists or sprays. Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Monitor area and confirm levels are below exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area

Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

Environmental precautions Sweep up and dispose of in accordance with Federal, State and local regulations.

7. HANDLING AND STORAGE

Precautions for safe handling Use only as directed. Avoid eye contact.

Conditions for safe storage, including any incompatibilities Use and store according to labelled directions. Do not store in unmarked or damaged containers or storage devices. Keep containers securely closed when not in use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PERSONAL PROTECTION:

Eye/face protection None required under normal conditions or use. Avoid eye contact, moderate irritation may result. May cause irritation in some sensitive individuals

Skin protection

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Hand protection	Not required under normal conditions of use. May cause skin irritation in some sensitive individuals.
Other	None required.
Respiratory protection	None required.
Thermal Hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking and/or smoking.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE	Viscuos Gel
Physical state	Semisolid
Form	Tube, Pump
Color	Off-white
ODOR	Not available
ODOR THRESHOLD	Not available
pH	Around 5.5 at 25°C
Melting point/freezing point	Not available
Initial boiling point and boiling	Not available
Flash point	Not available
Evaporation rate	Not available
Flammability (Solid/gas)	Not available
Vapour pressure	Not available
Vapour density	Not available
Relative density	Not available
Solubility	Not available
Partition coefficient	Not available

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Auto-ignition temperature Not available

Decomposition temperature Not available

Viscosity Not available

10. STABILITY AND REACTIVITY

Reactivity Stable

Chemical stability This product is stable.

Possibility of hazardous reactions If exposed to extremely high temperatures, products of thermal decomposition may include irritating vapours and toxic gases (e.g. oxides of carbon and nitrogen).

Conditions to avoid Open flames, high heat, direct sunlight and freezing

Incompatible materials Avoid oxidizers, acids and bases.

11. TOXICOLOGICAL INFORMATION

Inhalation Due to the form of this product, inhalation is unlikely. If vapours of the gel are inhaled, they may cause coughing and temporary bronchial irritation. Symptoms are generally alleviated upon breathing fresh air.

Skin contact Contact with the skin may cause mild to moderate irritation, depending on concentration and duration of exposure. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).

Eye contact Contact of this product with the eyes may cause mild irritation, redness, and tearing.

Ingestion Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product caused by poor hygiene practices may cause adverse symptoms. Symptoms of acute ingestion

overexposure can include upset stomach, vomiting, stomach pain

Aspiration hazard Not likely, due to the form of the product

Further information Finished product is not expected to be carcinogenic to humans.

12. ECOLOGICAL INFORMATION

Ecotoxicity All releases to terrestrial, atmospheric and aquatic environments should be avoided. No specific data is available for this product.

13. DISPOSAL CONSIDERATIONS

Dispose of waste in accordance with all Federal, State and local laws.

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14. TRANSPORT INFORMATION

DOT	This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.
IATA	This product is not classified as Dangerous Goods, by rules of IATA
IMDG	This product is not classified as Dangerous Goods by the International Maritime Organization.

15. REGULATORY INFORMATION

CERLCA	None
OSHA	This product contains no chemicals which are hazardous by definition of the Hazard Communication Standard (29 CFR 1910.1200).

16. OTHER INFORMATION

Contact Information	Encube Ethicals, Inc. 200 Meredith Avenue, Suite 101A, Durham, NC27713, USA https://www.encubeethicals.com/
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Disclaimer: This material safety data sheet has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

End of Safety Data Sheet