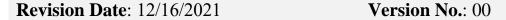
**Product Name:** ADAPALENE GEL USP, 0.3%





# 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

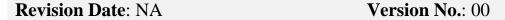
Water.

#### 4. FIRST-AID MEASURES

Product Name: ADAPALENE GEL USP, 0.3%

Specific methods

General fire hazards





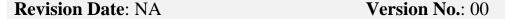
Inhalation	If respiratory irritation occurs, remove individual to fresh air
Skin contact	If redness, dryness or other signs of irritation occur wash the affected
	Area with warm water and soap. If irritation persists contact a
	Physician.
Eye contact	If the product is in the eyes, do not rub eyes. Flush 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 <sub>2</sub> , 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.
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other involved materials.

Use standard firefighting procedures and consider the hazards of

When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen

Product Name: ADAPALENE GEL USP, 0.3%





oxides).

#### 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-incidental 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 bellow 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:

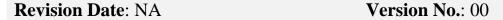
Eye/face protection

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

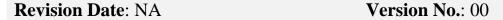
Vapour density Not available

Relative density Not available

Solubility Not available

Partition coefficient Not available

**Product Name**: ADAPALENE GEL USP, 0.3%





Auto-ignition temperature Not available

Decomposition temperature Not available

Viscosity Not available

### 10. STABILITY AND REACTIVITY

Reactivity Stable

Chemical stability This product is stable.

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

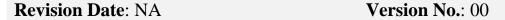
Ecotoxicity All releases to terrestrial, atmospheric and aquatic environments

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.

**Product Name**: ADAPALENE GEL USP, 0.3%





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 <a href="https://www.encubeethicals.com/">https://www.encubeethicals.com/</a>

**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**