

Material safety Data sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	Permethrin Cream 5% w/w
Registration number	-----
Synonyms	-----

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing Information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient. **Uses advised against** No other uses are advised.

1.3. Company Name:

Encube Ethicals Pvt. Ltd
Plot No.C-1, Madkaim Industrial Estate,
Madkaim, Post- Mardol, Ponda
Goa – 403 404
India
Tel. No.: +91-0832-6618600

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Not Applicable

2.2. Label elements

Not Applicable

Supplemental label information None.

2.3. Other hazards- Expected to be non-combustible.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Active Ingredient: Permethrin 5%

Inactive Ingredients:

Carbomer Homopolymer Type B: CAS- 9003-01-4

Medium chain Triglycerides: CAS- 73398-61-5

Glycerin: CAS- 56-81-5

Mono-di-glycerides: CAS-85251-77-0

Isopropyl Myristate: CAS-110-27-0

Lanolin Alcohols: ----

Mineral Oil: CAS-8042-47-5

Sodium Hydroxide: CAS: 1310-23-2

Formaldehyde: CAS-50-00-0

Polyoxyethylene 20 Cetyl Ether: ---

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SECTION 4: First aid measures

General information Take off all contaminated clothing immediately. Wash contaminated clothing before reuse. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

4.1. Description of first aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Take off immediately all contaminated clothing. Immediately flush skin with plenty of water. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do. Call a physician or poison control centre immediately.

Ingestion Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms The possible consequences of overexposure include: symptoms similar to alcohol intoxication, and **effects, both acute and** symptoms of hypersensitivity (such as skin rash, hives, itching).

4.3. Indication of any immediate medical attention No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards: Expected to be non-combustible.

5.1. Extinguishing media

Suitable extinguishing Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing: None known.

5.2. Special hazards arising During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting 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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended

6.2. Environmental precautions Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

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6.3. Methods and material for Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is **containment and cleaning up** possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

6.4. Reference to other For personal protection, see section 8. For waste disposal

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

7.2. Conditions for safe: Store in original tightly closed container. Store away from incompatible materials.

7.3. Specific end use(s): Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Components	Type	Value
PERMETHRIN (CAS- 52645-53-1)		200 mcg/m ³

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Recommended monitoring procedures	Follow standard monitoring procedures.
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Derived no-effect level (DNEL)	Not available.
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Predicted no effect concentrations (PNECs)	Not available.
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8.2. Exposure controls

Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation,
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General information	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Not normally needed.
Skin protection	
- Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. An occupational/industrial hygiene monitoring method has been developed for this material.
Environmental exposure controls	
Hazard guidance and	Contain spills and prevent releases and observe national regulations on emissions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Cream
Form	Cream.
Colour	White to off white
Odour	Not available.
Odour threshold	Not available.
pH	6.5-7.5
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

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Solubility (water)	Not available.
Solubility (other)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.
SECTION 10: Stability and reactivity	
10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.	
SECTION 11: Toxicological information	
General information	Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Ingestion	May be harmful if swallowed. Do not ingest. Health injuries are not known or expected under normal use.
Inhalation	Health injuries are not known or expected under normal use.
Skin contact	May be irritating to the skin. Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. May be irritating to eyes. Avoid contact with eyes.
Symptoms	The possible consequences of overexposure include: symptoms similar to alcohol intoxication, symptoms of hypersensitivity (such as skin rash, hives, itching).
11.1. Information on toxicological effects	
Acute toxicity	May be harmful if swallowed. Health injuries are not known or expected under normal use.
* in corrosion/irritation	May be irritating to the skin. Health injuries are not known or expected under normal use.
Serious eye damage/eye irritation	May be irritating to eyes. Health injuries are not known or expected under normal use.
Respiratory sensitisation	Health injuries are not known or expected under normal use.
Skin sensitisation	Health injuries are not known or expected under normal use.
Germ cell mutagenicity	Health injuries are not known or expected under normal use.
Carcinogenicity	Health injuries are not known or expected under normal use. Contains a material (formaldehyde)
Reproductive toxicity-	Health injuries are not known or expected under normal use.
Specific target organ toxicity -	None known.
Specific target organ toxicity -	None known.

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Aspiration hazard Not an aspiration hazard.
Mixture versus substance information No information available.
Other information Not available.

SECTION 12: Ecological information

12.1. Toxicity: The product contains a substance which may cause long-term adverse effects in the environment.

12.2. Persistence and No data is available on the degradability of this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

General Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

14.1. Transport hazard class(es): ----

14.2. Environmental hazards No.

14.6. Special precautions Not available.

Other information

Cargo aircraft only Allowed.

Additional Information:

Passenger & cargo Allowed.

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Marine pollutant



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SECTION 15: Regulatory information

National regulations Follow national regulation for work with chemical agents.

15.2. Chemical safety No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations Not available.

Information on evaluation The classification for health and environmental hazards is derived by a combination of calculation method leading to the methods and test data, if available.

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Full text of any statements or R-phrases and H-statements under Sections 2 to 15 R20/22 Harmful by inhalation and if swallowed.

R22 Harmful if swallowed.

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R34 Causes burns.

R35 Causes severe burns.

R40 Limited evidence of a carcinogenic effect.

R43 May cause sensitization by skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Authorized Signatory



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