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- MATERIAL SAFETY DATA SHEET -

SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Name : Roflumilast
Company Identification : Clearsynth Labs Pvt. Ltd.
413 Laxmi Mall, New Link Road, Andheri (W),
Mumbai-400 053, INDIA
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SECTION 2 - COMPOSITION, INFORMATION ON INGREDIENTS

CAS#	Chemical Name	%	EINECS#	Haz Symbols	RISK PHRASES
162401-32-3	Roflumilast	>95%	-	-	-

Hazard Symbols: XN

Risk Phrases: 22

SECTION 3 - HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Harmful if swallowed.

Potential Health Effects

The toxicological properties of this material have not been investigated. Use appropriate procedures to prevent opportunities for direct contact with the skin or eyes and to prevent inhalation. Compound is Non-hazardous, Non-Toxic/Non-Flammable.

SECTION 4 - FIRST AID MEASURES

Eyes:

Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids.

Skin:

Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

Ingestion:

Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cupfuls of milk or water.

Inhalation:

Remove from exposure and move to fresh air immediately.

Notes to Physician:

SECTION 5 - FIRE FIGHTING MEASURES

General Information:

As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or

combustion.

Extinguishing Media:

In case of fire, use water, dry chemical, chemical foam, or alcohol-resistant foam.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General Information: Use proper personal protective equipment as indicated in Section 8.

Spills/Leaks:

Clean up spills immediately, observing precautions in the Protective Equipment section. Sweep up, then place into a suitable container for disposal.

SECTION 7 - HANDLING and STORAGE

Handling:

Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation.

Storage:

Store in a well closed container.

SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:

Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits. Use process enclosure, local exhaust ventilation, or other engineering controls to control airborne levels.

Personal Protective Equipment

Eyes:

Wear safety glasses and chemical goggles if splashing is possible.

Skin:

Wear appropriate protective gloves and clothing to prevent skin exposure.

Clothing:

Wear appropriate protective clothing to minimize contact with skin.

Respirators:

Wear a NIOSH/MSHA or European Standard EN 149 approved full-facepiece airline respirator in the positive pressure mode with emergency escape provisions.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical State: _____

White to Off-White Solid

Molecular Formula: _____

C₁₇H₁₄Cl₂F₂N₂O₃

Molecular Weight: _____

403.21

SECTION 10 - STABILITY AND REACTIVITY

Chemical Stability:

Stable under normal temperatures and pressures.

Conditions to Avoid:

Incompatible materials, strong oxidants.

Incompatibilities with Other Materials:

Strong oxidizing agents, strong bases.

Hazardous Decomposition Products:

Nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide, nitrogen.

Hazardous Polymerization: Has not been reported.

SECTION 11 - TOXICOLOGICAL INFORMATION

RTECS#:

CAS#: LD50/LC50:

CAS#: Draize test, rabbit, eye: 100 mg/24H Moderate; Oral, mouse: LD50 = 300 mg/kg; Oral, rabbit: LD50 = 3200 mg/kg; Oral, rat: LD50 = 980 mg/kg.

Carcinogenicity:

Salicylamide -

Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA.

See actual entry in RTECS for complete information.

SECTION 12 - ECOLOGICAL INFORMATION

SECTION 13 - DISPOSAL CONSIDERATIONS

Dispose of in a manner consistent with federal, state, and local regulations.

SECTION 14 - TRANSPORT INFORMATION

IATA No information available.

IMO No information available.

ID/ADR No information available.

SECTION 15 - REGULATORY INFORMATION

European/International Regulations

European Labeling in Accordance with EC Directives

Hazard Symbols: XN

Risk Phrases:

R 22 Harmful if swallowed.

Safety Phrases:

WGK (Water Danger/Protection)

CAS# United Kingdom Occupational Exposure Limits

United Kingdom Maximum Exposure Limits

Canada

CAS# is listed on Canada's DSL List.

CAS# is not listed on Canada's Ingredient Disclosure List.

Exposure Limits

US FEDERAL

TSCA

CAS# is listed on the TSCA inventory.

SECTION 16 - ADDITIONAL INFORMATION

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.