Safety Data Sheet

SAFETY DATA SHEET - LC LABORATORIES
REVISION DATE: JULY 1, 2019

SECTION 1. IDENTIFICATION:

Trade name: Fingolimod, Hydrochloride Salt
Product Number: F-4633
Manufacturer/Supplier:
LC Laboratories
165 New Boston Street
Woburn, MA 01801 USA
1-781-937-0777 Fax: 1-781-938-5420

SECTION 2. HAZARD(S) IDENTIFICATION:

Hazard Description: Irritant; immunosuppressant
Substance Class Identifier: Drug
May be harmful if swallowed, inhaled, or absorbed through the skin
Causes irritation of the skin and eyes
Exposure may result in dyspnea (shortness of breath), infections such as colds and flu, nasopharyngitis (inflammation of the nose and throat), headache, diarrhea, nausea, bradycardia (slowed heart beat), hypertension (elevated blood pressure), cough, back pain, elevated liver enzymes, and macula edema (swelling or thickening of the area of the retina responsible for central vision)
Higher than expected rates of skin malignancies (basal cell carcinoma, squamous cell carcinoma, and melanoma) have also been observed in patients undergoing clinical trials with this compound
Exposure may cause irritation to the upper respiratory tract
Signal Word: Warning

GHS Hazard Statements:

H302+312+332 - Harmful if swallowed, in contact with skin or if inhaled

GHS Precautionary Statements:

P2562 - Do not get in eyes, on skin or on clothing
WARNING: For Laboratory Research Use Only

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS:

Chemical Name: 2-Amino-2-[2-(4-octylphenyl)ethyl]-1,3-propanediol hydrochloride
Synonyms: FTY-720A, FTY720, D04187, Gilenia, Gilenya
Hazardous Ingredient: Fingolimod, Hydrochloride Salt
CAS Registry Number: 162359-56-0

Molecular Weight: 343.93
Molecular Formula: $C_{19}H_{33}NO_2 \bullet HCl$

SECTION 4. FIRST-AID MEASURES:
After Inhalation: If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give artificial respiration
After skin contact: flush with copious amounts of water; remove contaminated clothing and shoes; call a physician
After eye contact: check for and remove contact lenses; flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician
After swallowing: if swallowed, wash out mouth with copious amounts of water; call a physician

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SECTION 5. FIRE-FIGHTING MEASURES:
Suitable extinguishing agents: water spray, carbon dioxide, dry chemical powder, or foam
Protective equipment: wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes
Unusual fire hazard: may emit toxic fumes under fire conditions such as carbon monoxide, etc.

SECTION 6. ACCIDENTAL RELEASE MEASURES:
Person-related safety precautions: cordon off area of spill; wear self-contained breathing apparatus, protective clothing and heavy rubber gloves
Measures for cleaning/collecting: absorb solutions with finely- powdered liquid-binding material (diatomite, universal binders); decontaminate surfaces and equipment by scrubbing with alcohol; dispose of contaminated material according to Section 13

SECTION 7. HANDLING AND STORAGE:
Information for safe handling: avoid contact with skin, eyes and clothing; material may be an irritant
Storage: store solid and solutions at -20 ºC

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION:
Personal protective equipment as follows:
Breathing equipment: NIOSH/MSHA-approved respirator
Protection of hands: handle with Nitrile rubber gloves with minimum thickness of 0.11 mm (4.3 mil). This recommendation should not be interpreted as offering an approval for any specific use conditions. Please review this recommendation with a safety officer to evaluate if it is appropriate for the anticipated use.
Eye protection: chemical safety goggles

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES:

Form: Crystalline solid; granular or powder
Color: white
Odor: none
Melting point/Melting range: not tested
Danger of explosion: none
Solubility in / Miscibility with water: very poorly soluble in water; up to 25 µL of a solution of 13.8 mg/mL (40 mM) fingolimod-HCl in 100% DMSO can be diluted into 5 mL of plain water without precipitation, giving a final concentration of 200 µM; in contrast, even a 1-to-1,000 dilution of the same 13.8 mg/mL DMSO stock solution into a 10 mM phosphate-buffered saline at pH 7 results in a precipitate; thus, fingolimod-HCl solubility in PBS is likely to be well below 100 µM, perhaps as low as 1-10 µg/mL; buffers, serum, or other additives may increase or decrease the aqueous solubility
Solvent content: none
Organic solvents: soluble in DMSO at 100 mg/mL; soluble in ethanol at 100 mg/mL

SECTION 10. STABILITY AND REACTIVITY:

Stability: stable if stored as directed; avoid strong oxidizing agents
Thermal decomposition / conditions to be avoided: protect from light and heat
Dangerous products of decomposition: thermal decomposition may produce toxic gases such as carbon monoxide, carbon dioxide, and nitrogen oxides

SECTION 11. TOXICOLOGICAL INFORMATION:

RTECS #: TY3130000
Acute toxicity: oral toxicity (TDLo): 0.3 mg/kg (rat), 0.1 mg/kg (monkey); intravenous toxicity (TDLo): 0.1 mg/kg (monkey)
Primary irritant effect:
On the skin: may be an irritant; may be harmful if absorbed through the skin
On the eye: may be an irritant
Inhalation: may cause irritation to mucous membranes and upper respiratory tract; may be harmful if inhaled
Ingestion: may be harmful if swallowed

SECTION 12. ECOLOGICAL INFORMATION:

Harmful to aquatic life with long lasting effects
Avoid release to the environment

SECTION 13. DISPOSAL CONSIDERATIONS:

Dispose of in accordance with prevailing country, federal, state and local regulations

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SECTION 14. TRANSPORT INFORMATION:
DOT:
Proper shipping name: none
Non-Hazardous for transport: this substance is considered to be non-hazardous for transport
IATA class:
Proper shipping name: none
Non-Hazardous for transport: this substance is considered to be non-hazardous for transport

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SECTION 15. REGULATORY INFORMATION:
Code letter and hazard designation of product:
Xi: Irritant; N:
EU Risk And Safety phrases:
S22: Do not breathe dust
S24/25: Avoid contact with skin and eyes
S36/37/39: Wear suitable protective clothing, gloves, and eye/face protection
R36/38: Irritating to eyes and skin
R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

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SECTION 16. OTHER INFORMATION:
The above information is believed to be correct based on our present knowledge but does not purport to be complete. For research use only by trained personnel. The burden of safe use of this material rests entirely with the user. LC Laboratories disclaims all liability
Reviewed: July 1, 2019