RSLAB
Precise is Safe

SAFETY DATA SHEET

1. Identification

Product name	Teriflunomide
Product code	RLP-T-0001-0
CAS number	163451-81-8
Chemical name	(Z)-2-Cyano-3-hydroxy-N-[4-(trifluoromethyl) phenyl] but-2-enamide.
Suggested use	Specified quality tests and assay use only.
Advised limitations	Not for use as a drug. Not for administration to humans or animals.
Manufacturer	Reflabpharm LLC
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2. Hazard(s) Identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 3
	Reproductive toxicity	Category 1
	Specific target organ toxicity, repeated exposure (immune system, liver)	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		
Signal word	Danger.	
Hazard statement	Toxic if swallowed. May damage fertility or the unborn child. Causes damage to organs (immune system, liver) through prolonged or repeated exposure.	
Precautionary statement		
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.	
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If exposed or concerned: Get medical advice/attention.	
Storage	Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	

Hazard(s) not otherwise classified (HNOC)	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.
Supplemental information	Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Teriflunomide	(Z)-2-Cyano-3-hydroxy-N-[4-(trifluoromethyl) phenyl] but-2-enamide.	163451-81-8	100

4. First-aid Measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting Measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO_2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to cool unopened containers.
Equipment	Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. For personal protection, see section "Personal Protection" of the SDS. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section "Disposal considerations" of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and Storage

Precautions for safe handling	As a general rule, when handling CRMs, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any incompatibilities	This material should be handled and stored per label instructions to ensure product integrity.

8. Personal Protection

Occupational exposure limits

Exposure limit values

Industrial Use Material	Type	Value
Teriflunomide (CAS163451-81-8)	TWA	0.007 mcg/m³

Appropriate engineering controls	For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.
Biological limit values	No biological exposure limits noted for the ingredient(s).

Individual protection measures

Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Other	Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
Respiratory protection	Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any lot.
Physical state	Solid.
Form	Powder.
Color	White.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting 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.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.

Solubility(ies)

Solubility (water)	Practically insoluble.
Solubility (other)	Methanol: Soluble. Ethanol: Slightly soluble. Dimethyl sulfoxide: Sparingly soluble. Isopropanol: Very slightly soluble. Acetone: Sparingly soluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

9.3 Other information

Molecular formula	$C_{12}H_9F_3N_2O_2$
Molecular weight	270.21

10.Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	F-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11.Toxicological Information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Toxic if swallowed. Based on information from therapeutic use, this material may cause: Liver damage.
Symptoms related to the physical, chemical, and toxicological characteristics	Pyrimidine synthesis inhibitors: Gastrointestinal disturbances. Increased liver enzymes. Blood disorders. Hypertension. Headache. Dizziness. Immunosuppression.

Information on toxicological effects

Acute toxicity	Toxic if swallowed.

Product	Species	Test Results
Teriflunomide (CAS 163451-81-8)		
Oral LD50	Rat	200 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.	
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Based on available data, the classification criteria are not met.	
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Mutagenicity	Ames test Result: Negative. Chromosome aberration Result: Negative. Chromosome aberration: human lymphocytes Result: Positive. Micronucleus test Result: Negative. Mutagenicity, In vitro HPRT assay Result: Negative.	
Carcinogenicity	Knowledge about carcinogenicity is incomplete. < 12 mg/kg/day Carcinogenicity Result: Negative. Species: Mouse Test Duration: 104 weeks 4 mg/kg/day Carcinogenicity Result: Negative. Species: Rat Test Duration: 104 weeks	
IARC Monographs. Overall Evaluation of Carcinogenicity	Not listed.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)	Not listed.	
Reproductive toxicity	May damage fertility or the unborn child. Pyrimidine synthesis inhibitors interfere with embryo development and viability at maternally toxic doses in animals.	
Reproductivity	0 - 8.6 mg/kg/day Reproductivity, Embryolethality, reduced fetal body weight and/or malformations. Result: Positive. Species: Rat	
Specific target organ toxicity - single exposure	Knowledge about health hazard is incomplete.	
Specific target organ toxicity - repeated exposure	Causes damage to organs (immune system, liver) through prolonged or repeated exposure.	
Aspiration hazard	Based on available data, the classification criteria are not met.	
Further information	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.	

12.Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data is available on the degradability of this substance.
Bioaccumulative potential	
Octanol/water partition coefficient log Kow	No data available.
Mobility in soil	No data available.

Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13.Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14.Transport information

DOT	UN2811
IATA	UN2811
General information	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15.Regulatory information

Safety, health and environmental regulations/legislation specific for the substance

This Safety Data Sheet has been prepared in accordance with applicable GHS principles for hazard communication.

Chemical safety assessment

A chemical safety assessment has not been carried out for this substance.

16.Other information, including date of preparation or last revision

Disclaimer	Reflabpharm CRMs are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein applies solely to the chemical substance when used as a Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). CRMs are intended for use by persons having technical skills and at their discretion and risk. This information has been developed by Reflabpharm staff from sources considered reliable but has not been independently verified by Reflabpharm. Therefore, the Reflabpharm cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made concerning the information contained herein.