

SAFETY DATA SHEET

Section 1: Identification	
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Material	Teriflunomide
CAT No.	AC467110000; AC467110010; AC467112500
CAS No.	163451-81-8
Synonyms	No information available
Recommended Use	Laboratory chemicals
Uses Advised Against	Food, drug, pesticide or biocidal product use
Distributor	SOLA Pharmaceuticals 655 Highlandia Drive, Ste B Baton Rouge, LA. 70810 Tel: 866.747.7365 Fax: 800.754.9550 www.solameds.us info@solameds.us
NDC Number	70512-848-30 (7mg 30's) 70512-849-30 (14mg 30's) 70512-850-38 (7mg Blister 28's) 70512-851-28 (14mg Blister 28's)
Section 2: Hazard(s) Identification	
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Classification This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).	
Acute oral toxicity	Category 4
<u>Label Elements</u>	
Signal Word	
Warning	
Hazard Statements	
Harmful if swallowed	
Precautionary Statements	
Prevention	
Wash face, hands and any exposed skin thoroughly after handling	
Do not eat, drink or smoke when using this product	
Ingestion	
IF SWALLOWED: Call a POISON CONTROL CENTER or doctor/physician if you feel unwell	
Rinse mouth	

Disposal
Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)
None identified

Section 3: Composition/Information on Ingredients

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Component	CAS No.	Weight %
Teriflunomide	163451-81-8	<=100
Lactose Monohydrate	64044-51-5	
Hydroxypropyl Cellulose EXF	9004-64-2	
Microcrystalline Cellulose PH102	9004-34-6	
Colloidal Silicon Dioxide	112926-00-8	
Magnesium Stearate MF-2-V	557-04-0	
Titanium Dioxide	13463-67-7	
Talc	14807-96-6	
Hypromellose, Unspecified	9004-65-3	
FD&C Blue No. 2 Aluminum Lake	9004-65-3	
FD&C Red No. 40	9004-65-3	

Section 4: First-Aid Measures

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General Advice	If symptoms persist, call a physician.
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
Most important symptoms And Effects	None reasonably foreseeable.
Note to Physician	Treat symptomatically.

Section 5: Fire-Fighting Measures

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Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Dry chemical, CO ₂ , water spray or alcohol-resistant foam.
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Unsuitable Extinguishing Media No information available

Flash Point Method No information available
No information available

Autoignition Temperature No information available

Explosion Limits

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Ariving From The Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

Carbon monoxide (CO). Carbon dioxide (CO₂). Hydrogen fluoride. Nitrogen oxides (NO_x).

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

Health	Flammability	Instability	Physical Hazards
2	1	0	N/A

Section 6: Accidental Release Measures

Section 6, Accidental Release Measures

Personal Precautions Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

Environmental Precautions Should not be released into the environment.

Methods for Containment And Clean Up Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

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Handling Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

Storage Keep container tightly closed in a dry and well-ventilated place. To maintain product quality. Store in freezer. Incompatible materials. Oxidizing agent.

Section 8: Exposure Controls / Personal Protection

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Exposure Guidelines	This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
Engineering Measures	Ensure adequate ventilation, especially in confined areas.
Personal Protective Equipment	
Eye/Face Protection	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA’s eye and face protection regulations in 29 CFR 1910.133 or European Standard EN 166.
Skin and Body	Wear appropriate protective gloves and clothing to prevent skin exposure.
Respiratory Protection	Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice.

Section 9: Physical and Chemical Properties

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Physical State	Solid
Appearance	White
Odor	No information available
Odor Threshold	No information available
pH	Not applicable
Melting Point/Range	229°C / 442.2° F
Boiling Point/Range	No information available
Flash Point	No information available
Evaporation Rate	Not applicable
Flammability (solid, gas)	No information available
Flammability or explosive limits	
Upper	No data available
Lower	no data available
Vapor Pressure	No information available
Vapor Density	Not applicable
Specific Gravity	No information available
Solubility	No information available
Partition coefficient; n-octanol/water	No data available
Autoignition Temperature	No information available
Decomposition Temperature	No information available
Viscosity	Not applicable
Molecular Formula	C12 H9 F3 N2 O2
Molecular Weight	270.21

Section 10: Stability and Reactivity															
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Reactive Hazard	None known, based on information available														
Stability	No information available														
Conditions to Avoid	Incompatible products														
Incompatible Materials	Oxidizing agent														
Hazardous Decomposition Products	Carbon monoxide (CO), Carbon dioxide (CO ₂), Hydrogen fluoride, Nitrogen oxides (NO _x)														
Hazardous Polymerization	Hazardous polymerization does not occur														
Hazardous Reactions	None under normal processing														
Section 11: Toxicological Information															
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<u>Acute Toxicity</u>															
Product Information															
Component Information															
Toxicologically Synergistic Products	No information available														
<u>Delayed and immediate effects as well as chronic effects from short and long-term exposure</u>															
Irritation	No information available														
Sensitization	No information available														
Carcinogenicity	The table below indicates whether each agency has listed any ingredients as a carcinogen														
<table border="1"> <thead> <tr> <th>Component</th> <th>CAS No.</th> <th>IARC</th> <th>NTP</th> <th>ACGIH</th> <th>OSHA</th> <th>Mexico</th> </tr> </thead> <tbody> <tr> <td>Teriflunomide</td> <td>163451-81-8</td> <td>Not listed</td> <td>Not listed</td> <td>Not listed</td> <td>Not listed</td> <td>Not listed</td> </tr> </tbody> </table>		Component	CAS No.	IARC	NTP	ACGIH	OSHA	Mexico	Teriflunomide	163451-81-8	Not listed	Not listed	Not listed	Not listed	Not listed
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Teriflunomide	163451-81-8	Not listed	Not listed	Not listed	Not listed	Not listed									
Mutagenic Effects	No information available														
Reproductive Effects	No information available														
Developmental Effects	No information available														
STOT – single exposure	None known														
STOT – repeated exposure	None known														
Aspiration Hazard	No information available														

Symptoms/effects, both acute and delayed	No information available
Endocrine Disruptor Information	No information available
Other Adverse Effects	The toxicological properties have not been fully investigated

Section 12: Ecological Information

Section 12, Ecological Information

Ecotoxicity Do not empty into drains.	
Persistence and Degradability	No information available
Bioaccumulation/Accumulation	No information available
Mobility	No information available

Component	Log Pow
Teriflunomide	2,92

Section 13: Disposal Considerations

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Waste Disposal Methods	Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.
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Section 14: Transport Information

Section 14, Transport Information

DOT	Not regulated
TDG	Not regulated
IATA	Not regulated
IMDG/IMO	Not regulated

Section 15: Regulatory Information

Section 15, Regulatory Information

United States of America Inventory

Component	CAS No.	TSCA	TSCA Inventory Notification – Active-Inactive	TSCA – EPA Regulatory Flags
Teriflunomide	163451-81-8	-	-	-

Legend:
TSCA US EPA (TSCA) – Toxic Substances Control Act (40 CFR Part 710)

X – Listed
 ‘-’ – Not listed

TSCA – Per 40 CFR 751, Regulation of Certain Chemical Substances & Mixtures, Under TSCA Section 6(h) (PBT) Not applicable

TSCA 12(b) – Notices of Export Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL)

Component	CAS No.	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Terilfunomide	163451-81-8	-	-	-	-	-	-	-	-	-

KECL – NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

U.S. Federal Regulations

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 21 for more information
CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA – Occupational Safety and Health Administration Not applicable

CERCLA Not applicable

California Proposition 65 This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations Not applicable

U.S. Department of Transportation

Reportable Quality (RQ): N
 DOT Marine Pollutant: N
 DOT Severe Marine Pollutant: N

U.S. Department of Homeland Security This product does not contain any DHS chemicals

Other International Regulations

Mexico – Grade No information available

Authorization/Restrictions According to EU REACH		Not applicable		
Component	CAS No.	REACH (1907/2006) – Annex XIV – Substances Subject to Authorization	REACH (1907/2006) – Annex XVII – Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) – Article 59 – Candidate List of Substances of Very High Concern (SVHC)
Teriflunomide	163451-81-8	-	-	-

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

Component	CAS No.	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Teriflunomide	163451-81-8	Not applicable	Not applicable	Not applicable	Not applicable

Component	CAS No.	Seveso III Directive (2012/18/EC) – Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) – Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
Teriflunomide	163451-81-8	Not applicable	Not applicable	Not applicable	Not applicable

Section 16: Other Information

Section 16, Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

SOLA shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.