



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

Label Elements
Signal Word
Warning

Hazard Statements

Harmful if swallowed

Precautionary Statements

Prevention

Wash face, hands and any exposed skin thoroughly after handling $% \left(1\right) =\left(1\right) \left(1\right) +\left(1\right) \left(1\right) \left(1\right) +\left(1\right) \left(1\right) \left$

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	

Secti	ion 4:	First-Aid	Measures

Section	4	First-	ΛhiΔ	/leasures

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 plency 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

of 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.

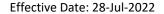
Note to Physician Treat symptomatically.

Section 5: Fire-Fighting Measures

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Suitable Extinguishing Use extinguishing measures that are appropriate to local circumstances and the

Media surrounding environment. Dry chemical, CO₂, water spray or alcohol-resistant foam.





Unsuitable Extinguishing

No information available

Media

Flash Point No information available Method No information available

Autoignition Temperature No information available

Explosion Limits

UpperNo data availableLowerNo data available

Sensitivity to

No information available

Mechanical Impact

Sensitivity to No information available

Static Discharge

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 (NOx).

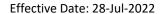
Protective Equipment and Precautions for Firefighters

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	Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed					
And Clean Up	containers for disposal.					
	Section 7: Handling and Storage					
Section 7, Handling and Storag	ge					
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

OdorNo information availableOdor ThresholdNo information available

pH Not applicable **Melting Point/Range** 229°C / 442.2° F

Boilding Point/RangeNo information available **Flash Point**No information available

Evaporation Rate Not applicable

Flammability (solid, gas) No information available

Flammability or explosive limits

UpperNo data availableLowerno data available

Vapor Pressure No information available

Vapor Density Not applicable

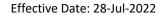
Specific GravityNo information availableSolubilityNo information available

Partition coefficient; n-octanol/water No data available

Autoignition TemperatureNo information availableDecomposition TemperatureNo information available

ViscosityNot applicableMolecular FormulaC12 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 (CO₂), Hydrogen fluoride, Nitrogen

oxides (NOx)

Hazardous Polymerization Hazardous polymerization does not occur

Hazardous Reactions None under normal processing

Section 11: Toxicological Information

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Acute Toxicity

Product Information Component Information

Toxicologically Synergistic No information available

Products

Delayed and iommediate effects as well as chronic effects from short and long-term exposure

Irritation No information available

Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredients as a

carcinogen

Component	ponent CAS No. IARC NTP		ACGIH	OSHA	Mexico	
Teriflunomide	163451-81-8	Not listed				

Mutagenic Effects No information available

Reproductive EffectsNo information available

Developmental EffectsNo information available

STOT – single exposure STOT – repeated exposureNone known
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.

Section 14: Transport Information

Section 14, Transport Information

DOT **TDG** Not regulated Not regulated

IATA

IMDG/IMO

Not regulated Not regulated

Section 15: Regulatory Information

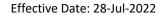
Section 15, Regulatory Information

United States of America Inventory

	Component	CAS No.	TSCA	TSCA Inventory Notification – Active-Inactive	TSCA – EPA Regulatory
L				Active-illactive	Flags
Ī	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	-	-	-	-	-	-	-	1	-

See section 21 for more information

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

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): Ν **DOT Marine Pollutant:** Ν **DOT Severe Marine Pollutant:** Ν

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.