



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
Material	Dimethyl Fumarate Delayed-Release Capsules, 120 mg and 240 mg
Manufacturer	Hetero Labs Limited Unit III 22-110, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	Camber Pharmaceuticals, Inc., Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard Class / Category	Skin Sensitization – Category 1 Skin Irritant – Category 2 Eye Irritant – Category 2 Acute dermal – Category 4 Hazards to the aquatic environment – Chronic, Category 2
Hazard Warning	Warning
Hazard Statements	H 317 – May cause allergic skin reaction H 315 – Causes skin irritation H 319 – Causes serious eye irritation H 312 – Harmful in contact with skin H 411 – Toxic to aquatic life with long lasting effects
Precautionary Statements:	<ol style="list-style-type: none">1. Avoid breathing dust/fumes/gas/mist/vapors/spray.2. Do not eat, drink or smoke when using this product3. Contaminated work clothing should not be allowed out of the workplace4. Wear protective gloves/protective clothing/eye protection/face protection.5. Wash hands thoroughly after handling.6. Avoid release to the environment.7. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.8. If eye irritation persists get medical advice/attention.9. IF ON SKIN: Wash with plenty of water10. If skin irritation or a rash occurs: Get medical advice/attention.11. Wash contaminated clothing before reuse.



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	12. Take off contaminated clothing.
	13. Collect spillage
	14. Dispose of contents/container in accordance with local/regional/national/international regulations
Other Hazard Information	CAUTION! This product contains an active pharmaceutical ingredient. The hazards of this compound have not been fully investigated. Use care when handling this material, avoid all contact.

Section 3: Composition/Information on Ingredients

Ingredients	Dimethyl fumarate
CAS	624-49-7

Section 4: First-Aid Measures

Ingestion	Rinse mouth with water and seek medical attention.
Inhalation	Move person to the fresh air. If not breathing give artificial respiration, treat symptomatically and supportively, get medical attention
Skin Contact	Remove contaminated clothing. If skin irritation or rash occurs: Get medical advice wash with plenty of soap and water For specific treatment see label Contaminated work clothing should not be allowed out of the workplace
Eye Contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures	
Suitable Extinguishing Media	Use water spray, carbon dioxide, ABC dry chemical or foam
Unsuitable Extinguishing Media / Unusual Risks	None Known
Special Fire-Fighting Equipment for Fire-Fighters	No data available

Section 6: Accidental Release Measures

Personal Precautions and Protection	Wear impervious gloves, suitable impervious coveralls and consider use of respiratory protection based on inhalation exposure risk.
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Environmental Precautions Follow federal, state and local discharge rules.

Clean-up Methods Place clean up debris in appropriate containers and dispose of in accordance with local, state and federal laws regarding waste management

Section 7: Handling and Storage

HANDLING Open handling of large amounts of capsules should be limited.

General Requirements Do not get in eyes on skin or on clothing
Wash hands thoroughly after handling
Do not eat, drink or smoke when handling

Storage Store in tightly sealed vial or container; avoid exposures to this material

Section 8: Exposure Controls/Personal Protection

The physical, chemical and occupational toxicological properties of this material have not been thoroughly investigated. Use caution when handling and avoid exposure. A comprehensive risk assessment for a particular operation should be performed to determine appropriate exposure controls.

Exposure Routes

Inhalation, skin and eye contact and accidental ingestion.

Engineering Controls

Perform operations that generate dust or vapors in an appropriate exhausted enclosure (fume hood or vented balance enclosure), glove box or isolator.

Respiratory Protection: Consult with an industrial hygienist / safety professional to determine appropriate respiratory protection needs based on the risk of inhalation. Active ingredient is known to sublime at room temperature therefore any open handling must consider vapors as well as dust exposures as part of handling risk assessment.

Other PPE: Wear protective gloves/protective clothing/eye protection/face protection.

Dimethyl fumarate vapors may penetrate through protective clothing. Appropriate coveralls and gloves should be selected based on breakthrough time of any PPE material selected.

Section 9: Physical and Chemical Properties

Appearance	Capsule
Color	As per Description
Physical State	Solid



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Description

Dimethyl fumarate is available as hard gelatin delayed-release capsules in two strengths containing either 120 mg or 240 mg of dimethyl fumarate.

They are available as follows:

30-day Starter Pack NDC 31722-680-60

7-day bottle 120 mg capsules, quantity 14

23-day bottle 240 mg capsules, quantity 46

The 120 mg capsules are light blue opaque size '0' hard gelatin capsules imprinted with 'H' on cap and 'D12' on body filled with white to off white tablets:

7-day bottle of 14 capsules NDC 31722-657-31

Blister Pack of 100 (10x10) unit dose capsules
NDC 31722-657-32

The 240 mg capsules are white opaque size '0el' hard gelatin capsules imprinted with 'H' on cap and 'D15' on body filled with white to off white tablets.

23-day bottle of 46 capsules NDC 31722-658-31

30-day bottle of 60 capsules NDC 31722-658-32

Blister Pack of 100 (10x10) unit dose capsules
NDC 31722-658-33

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Protect the capsules from light. Store in original container.

Section 10: Stability and Reactivity

Stability

Stable; non-hygroscopic

Incompatible materials / conditions

None

Hazardous decomposition products

None

Hazardous polymerization

None

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Acute Toxicity (DMF)

LD50 - oral - rat – 2.24 g/kg

LD50 – oral – rat, males – 4.75 g/kg

LD50 – oral – rat, females – 2.63

LD50 skin – rabbit – 1.25 g/kg

LCLo inhalation – mouse > 3100 mg/m³ for 10 hour exposure

Signs and Symptoms of

Irritation of the eyes, skin and upper respiratory tract. May cause

Exposure

dermatitis. May cause symptoms of airborne allergen exposure.

Effects by inhalation, dermal

Skin – rabbit – moderate irritant



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contact, ingestion or eye contact	Eye – rabbit – severe irritant
Sensitization	DMF was shown to be a moderate contact skin sensitizer in the guinea pig maximization test and in a guinea pig ear swelling test. DMF has been shown to rapidly provoke dermal irritation and to cause contact dermatitis in humans. No definitive data related to sensitization of the respiratory tract has been identified.
Chronic Toxicity	Dimethyl fumarate has been administered to rats for up to 6 months, dogs for 11 months, and monkeys for one year. The kidney is the target organ common to all species. Dimethyl fumarate has been administered orally to patients for treatment of psoriasis and for the treatment of multiple sclerosis. Patients have received dimethyl fumarate for up to 2 years in clinical trials. Effects of treatment included: flushing, nausea, vomiting and diarrhea.
Carcinogenicity	A 2-year oral carcinogenicity study was conducted in rats and mice. In the rat increases in renal cancers, carcinoma of the non-glandular stomach, interstitial cell adenoma of the testis and parathyroid adenoma were observed. In the mouse, increases in tumors of the non-glandular stomach and the kidney were seen.
Genotoxicity	Negative in the Ames microbial mutagenicity assay, the V-79 mammalian cell mutagenicity assay and in the in vitro chromosome aberration assay in peripheral human lymphocytes. Negative in the in vivo rat micronucleus assay.
Reproductive Toxicity	No effects on male or female fertility were seen in in rats. In the multigeneration study in rats, the maternal NOAEL was 25 mg/kg/day and the developmental viability and growth of the offspring was 100 mg/kg/day.
Teratogenicity	DMF was not teratogenic in rats or rabbits at doses evaluated (250 and 150 mg/kg/day, respectively).
Target Organs	Skin

Section 12: Ecological Information

Ecotoxicity	NOEC - activated sludge respiration inhibition test (ASRIT) = 2 mg/L. NOEC – algal growth inhibition test = 0.037 mg/L.
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	NOEC – Daphnia magna reproduction test = 0.0559 mg/L.
	NOEC – Fish early life stage test = 0.0457 mg/L.
Mobility	Not data available.
Environmental persistence	DMF is readily biodegradable. DMF was not stable enough in aqueous solution to measure sludge adsorption

Section 13: Disposal Considerations

Product Disposal	Follow federal, state, and local environmental regulations for disposal requirements.
Packaging Disposal	Follow federal, state, and local environmental regulations for disposal requirements
Other regulatory information	None

Section 14: Transport Information

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Issue Date : 27-08-2020

Version : 00

Further information

Revision date: New issue

Revision note: New issue

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.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.