

SAFETY DATA SHEET

Section 1: Identification	
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Material	Dimethyl fumarate
Product Name	Dimethyl Fumarate Capsules 120mg/240mg
CAT No.	AC222180000; AC222180250; AC222181000; AC222185000
Synonyms	Allomaleic Acid Dimethyl Ester; Fumaric Acid; Dimethyl Ester
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	70512-852-14 (120mg 14's) 70512-853-60 (240mg 60'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 dermal toxicity	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2
Skin sensitization	Category 1
Specific target organ toxicity (single exposure)	Category 3
Target organs – Respiratory system	
Label Elements	
Signal Word	
Warning	
Hazard Statements	
Harmful in contact with skin	
Causes skin irritation	

Causes serious eye irritation
 May cause an allergic skin reaction
 May cause respiratory irritation

Precautionary Statements

Prevention

Wear protective gloves/protective clothing/eye protection/face protection
 Wash face, hands and any exposed skin thoroughly after handling
 Avoid breathing dust/fume/gas/mist/vapors/spray
 Contaminated work clothing should not be allowed out of the workplace
 Use only outdoors in a well-ventilated area

Inhalation

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
 Call a POISON CENTER or doctor/physician if you feel unwell

Skin

IF ON SKIN: Wash with plenty of soap and water
 Call a POISON CENTER or doctor/physician if you feel unwell
 Take off contaminated clothing and wash before reuse
 If skin irritation or rash occurs: Get medical advice/attention

Eyes

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
 Continue rinsing.
 If eye irritation persists, get medical advice/attention

Storage

Store in a well-ventilated place. Keep container tightly closed.
 Store locked up.

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 %
2-Butenedioic acid (E)-, dimethyl ester	624-49-7	>95
Colloidal Silicon Dioxide	14808-60-7	
Croscarmellose Sodium	74811-65-7	
Alcohol	54-17-5	
Magnesium Stearate	557-04-0	
Methacrylic Acid – Ethyl Acrylate Copolymer (4500 MPA.S)	25212-88-8	

Methacrylic Acid and Ethyl Acrylate Copolymer	25212-88-8	
Microcrystalline Cellulose	9004-34-6	
Water	7732-18-5	
Talc	14807-96-6	
Triethyl Citrate	77-93-0	
FD&C Blue No. 1	3844-45-9	
Ethyl Alcohol 96% ^{1/2} (240mg potency)	64-17-5	
Gelatin, Unspecified	9000-70-8	
Ferrosoferric Oxide	1309-37-1	
Ferric Oxide Yellow	51274-00-1	
Titanium Dioxide	13463-67-7	

¹Not present in finished product

²Based on drug product's posology and administration scheme, the estimated maximum ethanol daily intake is well below the threshold level defined at ICH guideline Q3C (R6)- 50mg per day for Class 3 residual solvents.

Section 4: First-Aid Measures

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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. Get medical attention.
Inhalation	Remove to fresh air. Do not use mouth-to-mouth if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention. If not breathing, give artificial respiration.
Ingestion	Do NOT induce vomiting. Call a physician or poison control center immediately.
Most important symptoms And effects	May cause allergic skin reaction. Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing.
Notes to Physician	Treat symptomatically.

Section 5: Fire-Fighting Measures

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Suitable Extinguishing Media	Water spray, carbon dioxide (CO ₂), dry chemical, alcohol-resistant foam
Unsuitable Extinguishing Media	No information available
Flash Point	No information available
Method	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 Arising from the Chemical	
Keep product and empty container away from heat and sources of ignition.	
Hazardous Combustion Products	
Carbon monoxide (CO). Carbon dioxide (CO ₂).	
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. Thermal decomposition can lead to release of irritating gases and vapors.	
NFPA	
Health	Flammability
2	1
	Instability
	0
	Physical Hazards
	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. See Section 12 for additional Ecological Information.
Methods for Containment And Clean Up	Sweep up and shovel into suitable containers for disposal. Avoid dust formation.
Section 7: Handling and Storage	
Section 7, Handling and Storage	
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 containers tightly closed in a dry, cool and well-ventilated place. Incompatible Materials. Acids. Bases. Reducing Agent. Oxidizing agent.
Section 8: Exposure Controls / Personal Protection	
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Exposure Guidelines	This product not not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
Engineering Measures	Ensure that eyewash stations and safety showers are close to the workstation location. 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 Protection	Wear appropriate protective gloves and clothing to prevent skin exposure.
Respiratory Protection	Follow the OSHA respiratory 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 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	Odorless
Odor Threshold	No information available
pH	4.0 – 6.0 @ 20°C 1% susp
Melting Point/Range	102 – 105°C / 215.6 – 221°F
Boiling Point/Range	192 – 193°C / 377.6 – 379.4°F @ 760mmHg
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	C6 H8 O4
Molecular Weight	144.13

Section 10: Stability and Reactivity

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Reactive Hazard	None known, based on information available.
Stability	Stable under normal conditions.
Conditions to Avoid	Incompatible products. Excess heat. Avoid dust formation.
Incompatible Materials	Acids, Bases, Reducing Agent, Oxidizing Agent

Hazardous Decomposition Products	Carbon Monoxide (CO), Carbon Dioxide (CO ₂)					
Hazardous Polymerization	No information available.					
Hazardous Reactions	None under normal processing					
Section 11: Toxicological Information						
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Acute Toxicity						
Product Information						
Component Information						
	LD50 Oral	LD50 Dermal	LC50 Inhalation			
2-Butenedioic Acid (E)-, dimethyl ester	LD50: 240mg/kg (Rat)	LD50 = 1259mg/kg (Rabbit)	Not listed			
Toxicologically Synergistic	No information available					
Products						
Delayed and Immediate Effects As Well As Chronic Effects From Short and Long-Term Exposure						
Irritation	No information available					
Sensitization	May cause sensitization by skin contact					
Carcinogenicity	The table below indicates whether each Agency has listed any ingredient as a carcinogen.					
	CAS No.	IARC	NTP	ACGIH	OSHA	Mexico
2-Butenedioic Acid (E)-, dimethyl ester	624-49-7	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					
Teratogenicity	No information available					
STOT – single exposure	Respiratory system					
STOT – repeated exposure	None known					
Aspiration Hazard	No information available					
Symptoms/effects, Both Acute and Delayed	Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest Pain, muscle pain or flushing					

Endocrine Disruptor Information	No information available			
Other Adverse Effects	The toxicological properties have not been fully investigated			
Section 12: Ecological Information				
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Ecotoxicity Do not empty into drains.				
Component	Freshwater Algae	Freshwater Fish	Microtox	Water Flea
2-Butenedioic Acid (E)-, dimethyl ester	Not listed	Not listed	Not listed	EC50: 1.2mg/L/48h
Persistence and Degradability	Persistence is unlikely.			
Bioaccumulation/Accumulation	No information available			
Mobility	Will likely be mobile in the environment due to its water solubility.			
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	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
2-Butenedioic Acid (E)-, dimethyl ester	624-49-7	X	ACTIVE	---
<i>Legend:</i> TSCA US EPA (TSCA) – Toxic Substances Control Act; 40 CFR Part 710 X Listed “---” Not listed				
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
2-Butenedioic Acid (E)-, dimethyl ester	624-49-7	---	X	210-849-0	X	X	X	X	X	KE-11412

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 2 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 Quantity (RQ) N

DOT Marine Pollutant N

DOT Severe Marine Pollutant N

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

Other International Regulations

Mexico – Grade No information available

Authorization/Restriction According to EU REACH

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)
2-Butenedioic Acid (E)-, dimethyl ester	624-49-7	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)
2-Butenedioic Acid (E)-, dimethyl ester	624-49-7	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.