

SAFETY DATA SHEET



Felbamate Suspension Formulation



Version 2.1 Revision Date: 30.09.2023 SDS Number: 2364241-00012 Date of last issue: 04.04.2023
Date of first issue: 11.01.2018

Section 1: Identification

Product name : Felbamate Suspension Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : +1-551-430-6000

Emergency telephone number : +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

Section 2: Hazard identification

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Glycerine	56-81-5	>= 10 -< 20
2-phenylpropane-1,3-diyl dicarbamate	25451-15-4	>= 10 -< 20
Cellulose	9004-34-6	>= 1 -< 10

Section 4: First-aid measures

If inhaled : If inhaled, remove to fresh air.

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In case of skin contact	:	Get medical attention if symptoms occur. Wash with water and soap as a precaution.
In case of eye contact	:	Get medical attention if symptoms occur. Flush eyes with water as a precaution.
If swallowed	:	Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Protection of first-aiders	:	No special precautions are necessary for first aid responders.
Notes to physician	:	Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NO _x)
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures	:	Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate contain-

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ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labelled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Glycerine	56-81-5	WES-TWA (Mist)	10 mg/m ³	NZ OEL
2-phenylpropane-1,3-diyl di-carbamate	25451-15-4	TWA	400 µg/m ³ (OEB 2)	Internal
Cellulose	9004-34-6	WES-TWA	10 mg/m ³	NZ OEL
		TWA	10 mg/m ³	ACGIH

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Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Hand protection :
Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

Section 9: Physical and chemical properties

Appearance : suspension

Colour : Pinkish beige

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

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Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle size : Not applicable

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

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Components:

Glycerine:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

2-phenylpropane-1,3-diyl dicarbamate:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
LD50 (Mouse): > 5,000 mg/kg

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Glycerine:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Glycerine:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

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Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**Glycerine:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

2-phenylpropane-1,3-diyl dicarbamate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Result: negative

Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Glycerine:**

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

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2-phenylpropane-1,3-diyl dicarbamate:

Species : Mouse
 Application Route : Oral
 Exposure time : 92 weeks
 LOAEL : 300 mg/kg body weight
 Target Organs : Liver

Species : Rat
 Application Route : Oral
 Exposure time : 104 weeks
 NOAEL : 30 mg/kg body weight
 Target Organs : Liver, Testes
 Remarks : Benign tumor(s)

Cellulose:

Species : Rat
 Application Route : Ingestion
 Exposure time : 72 weeks
 Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Glycerine:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Ingestion
 Result: negative

2-phenylpropane-1,3-diyl dicarbamate:

Effects on fertility : Test Type: Fertility
 Species: Rat
 Application Route: Oral
 Fertility: NOAEL: 1,000 mg/kg body weight
 Remarks: No significant adverse effects were reported

Effects on foetal development : Test Type: Development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: NOAEL: 500 mg/kg body weight
 Result: Reduced foetal weight, Embryotoxic effects and adverse effects on the offspring were detected only at high ma-

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ternally toxic doses

Test Type: Development
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: NOAEL: 300 mg/kg body weight
 Result: Embryotoxic effects and adverse effects on the off-spring were detected only at high maternally toxic doses

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Ingestion
 Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Glycerine:

Species : Rat
 NOAEL : 0.167 mg/l
 LOAEL : 0.622 mg/l
 Application Route : inhalation (dust/mist/fume)
 Exposure time : 13 Weeks

Species : Rat
 NOAEL : 8,000 - 10,000 mg/kg
 Application Route : Ingestion
 Exposure time : 2 yr

Species : Rabbit
 NOAEL : 5,040 mg/kg
 Application Route : Skin contact
 Exposure time : 45 Weeks

2-phenylpropane-1,3-diyl dicarbamate:

Species : Rat
 NOAEL : 100 mg/kg
 Application Route : Oral

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Exposure time : 3 Months
Target Organs : Liver
Remarks : May cause damage to organs.

Species : Dog
NOAEL : 280 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Liver, Central nervous system

Species : Rat
NOAEL : 30 mg/kg
Application Route : Oral
Exposure time : 1 yr
Target Organs : Liver
Remarks : May cause damage to organs.

Species : Dog
NOAEL : 30 mg/kg
Application Route : Oral
Exposure time : 1 yr
Target Organs : Liver, Central nervous system
Remarks : May cause damage to organs.

Cellulose:

Species : Rat
NOAEL : $\geq 9,000$ mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

2-phenylpropane-1,3-diyl dicarbamate:

Ingestion : Target Organs: Liver
Symptoms: anorexia, Nausea, Vomiting, Headache, Dizziness, insomnia, Drowsiness

Section 12: Ecological information

Ecotoxicity

Components:

Glycerine:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
Exposure time: 96 h

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,955 mg/l
Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10,000 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

2-phenylpropane-1,3-diyl dicarbamate:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Persistence and degradability**Components:****Glycerine:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 %
Exposure time: 30 d
Method: OECD Test Guideline 301D

2-phenylpropane-1,3-diyl dicarbamate:

Stability in water : Hydrolysis: < 10 %(5 d)

Cellulose:

Biodegradability : Result: Readily biodegradable.

Bioaccumulative potential**Components:****Glycerine:**

Partition coefficient: n-octanol/water : log Pow: -1.75

2-phenylpropane-1,3-diyl dicarbamate:

Partition coefficient: n-octanol/water : log Pow: 0.381

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Mobility in soil

No data available

Other adverse effects

No data available

Section 13: Disposal considerations

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

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NZS 5433

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Hazchem Code	:	Not applicable

Special precautions for user

Not applicable

Section 15: Regulatory information

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

HSNO Approval Number

Not applicable

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

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Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

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AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NZ / EN