

## Felbamate Suspension Formulation

Version 1.6      Revision Date: 28.09.2020      SDS Number: 2368150-00007      Date of last issue: 23.03.2020  
Date of first issue: 11.01.2018

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**SECTION 1. PRODUCT AND COMPANY 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 : 551-430-6000

Emergency telephone : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture.

**Other hazards which do not result in classification**

None known.

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**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 -< 5

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**SECTION 4. FIRST AID MEASURES**

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.  
Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

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## Felbamate Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.6	28.09.2020	2368150-00007	Date of first issue: 11.01.2018

---

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.

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### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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<sub>x</sub>)

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 fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

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### 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 diking or other appropriate containment to keep material from spreading. If diked 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

## Felbamate Suspension Formulation

Version 1.6      Revision Date: 28.09.2020      SDS Number: 2368150-00007      Date of last issue: 23.03.2020  
Date of first issue: 11.01.2018

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.
- Conditions for safe storage : Keep in properly labeled 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

#### Ingredients with workplace control parameters

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

- 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 vapor type
- Hand protection : Chemical-resistant gloves
- Material
- 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

# SAFETY DATA SHEET



## Felbamate Suspension Formulation



Version 1.6      Revision Date: 28.09.2020      SDS Number: 2368150-00007      Date of last issue: 23.03.2020  
Date of first issue: 11.01.2018

---

Skin and body protection : aerosols.  
Hygiene measures : Work uniform or laboratory coat.  
: 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.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension  
Color : Pinkish beige  
Odor : No data available  
Odor 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  
Lower explosion limit / Lower flammability limit : No data available  
Vapor pressure : No data available  
Relative vapor density : No data available  
Relative density : No data available  
Density : No data available  
Solubility(ies)  
Water solubility : No data available

## Felbamate Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.6	28.09.2020	2368150-00007	Date of first issue: 11.01.2018

---

Partition coefficient: n-octanol/water	:	Not applicable
Autoignition 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

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**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.

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**SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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**Acute toxicity**

Not classified based on available information.

**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

---

## Felbamate Suspension Formulation

Version 1.6      Revision Date: 28.09.2020      SDS Number: 2368150-00007      Date of last issue: 23.03.2020  
Date of first issue: 11.01.2018

---

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 sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**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

## Felbamate Suspension Formulation

Version 1.6      Revision Date: 28.09.2020      SDS Number: 2368150-00007      Date of last issue: 23.03.2020  
Date of first issue: 11.01.2018

---

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

**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:**

## Felbamate Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.6	28.09.2020	2368150-00007	Date of first issue: 11.01.2018

---

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

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



## Felbamate Suspension Formulation

Version 1.6      Revision Date: 28.09.2020      SDS Number: 2368150-00007      Date of last issue: 23.03.2020  
Date of first issue: 11.01.2018

---

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 y

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  
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 y  
Target Organs : Liver  
Remarks : May cause damage to organs.

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

**Cellulose:**

Species : Rat  
NOAEL : >= 9.000 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

**Aspiration toxicity**

Not classified based on available information.

## Felbamate Suspension Formulation

Version 1.6      Revision Date: 28.09.2020      SDS Number: 2368150-00007      Date of last issue: 23.03.2020  
Date of first issue: 11.01.2018

---

**Experience with human exposure****Components:****2-phenylpropane-1,3-diyl dicarbamate:**

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

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Glycerine:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54.000 mg/l  
Exposure time: 96 h

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)

## Felbamate Suspension Formulation

Version 1.6      Revision Date: 28.09.2020      SDS Number: 2368150-00007      Date of last issue: 23.03.2020  
Date of first issue: 11.01.2018

---

### 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

#### Mobility in soil

No data available

#### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : 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.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

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## SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

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# SAFETY DATA SHEET



## Felbamate Suspension Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.6	28.09.2020	2368150-00007	Date of first issue: 11.01.2018

Control of precursors and essential chemicals for the preparation of drugs : Not applicable

### International Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

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

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
AR OEL / CMP : TLV (Threshold Limit Value)

AIC - 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 - Transporta-

# SAFETY DATA SHEET



## Felbamate Suspension Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.6	28.09.2020	2368150-00007	Date of first issue: 11.01.2018

---

tion of Dangerous Goods; 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.

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