SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Felbamate Suspension Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Felbamate Suspension Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : Organon & Co.
              30 Hudson Street, 33nd floor
              07302 Jersey City, New Jersey, U.S.A
   Telephone : 551-430-6000
   E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number
   215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
      Not a hazardous substance or mixture.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
      Not a hazardous substance or mixture.

2.3 Other hazards
   This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

   Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

   Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Felbamate Suspension Formulation

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2-phenylpropane-1,3-diyl dicarbamate</td>
<td>25451-15-4</td>
<td>247-001-4</td>
<td></td>
<td></td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- **Protection of first-aiders**: No special precautions are necessary for first aid responders.

- **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.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

- **Treatment**: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- **Suitable extinguishing media**: Water spray
  Alcohol-resistant foam
  Carbon dioxide (CO2)
  Dry chemical

- **Unsuitable extinguishing media**: None known.
5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Nitrogen oxides (NOx)

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.
SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage:
- Do not store with the following product types:
  - Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-phenylpropane-1,3-diy diicarbamate</td>
<td>25451-15-4</td>
<td>TWA</td>
<td>400 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m3</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local ef.</td>
<td>56 mg/m3</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**  
according to Regulation (EC) No. 1907/2006

**Felbamate Suspension Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.3</td>
<td>09.04.2021</td>
<td>2368139-00009</td>
<td>28.09.2020</td>
<td>11.01.2018</td>
</tr>
</tbody>
</table>

### Effects

#### Consumers
- **Ingestion**  
  **Long-term systemic effects**  
  - 229 mg/kg bw/day

#### Consumers
- **Inhalation**  
  **Long-term local effects**  
  - 33 mg/m3

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>Fresh water</td>
<td>0.885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>8.85 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>3.3 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.33 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.141 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

### Exposure controls

#### 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

- **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.

- **Hand protection**: Chemical-resistant gloves

- **Skin and body protection**: Work uniform or laboratory coat.

- **Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
  - Equipment should conform to I.S. EN 14387

- **Filter type**: Combined particulates and organic vapour type (A-P)

### SECTION 9: Physical and chemical properties

#### Information on basic physical and chemical properties

- **Physical state**: Suspension
- **Colour**: Pinkish beige
- **Odour**: No data available
- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
Initial boiling point and boiling range: 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
Flash point: No data available
Auto-ignition temperature: No data available
Decomposition temperature Decomposition temperature: No data available
pH: No data available
Viscosity Viscosity, kinematic: No data available
Solubility(ies) Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Vapour pressure: No data available
Relative density: No data available
Density: No data available
Relative vapour density: No data available
Particle characteristics Particle size: Not applicable

9.2 Other information
Explosives: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.
10.2 Chemical stability
   Stable under normal conditions.

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

10.4 Conditions to avoid
   Conditions to avoid : None known.

10.5 Incompatible materials
   Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
   No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
   Information on likely routes of exposure:
   Inhalation
   Skin contact
   Ingestion
   Eye contact

   Acute toxicity
   Not classified based on available information.

   Components:
   2-phenylpropane-1,3-diyl dicarbamate:
   Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
                       : LD50 (Mouse): > 5,000 mg/kg

   Skin corrosion/irritation
   Not classified based on available information.

   Serious eye damage/eye irritation
   Not classified based on available information.

   Respiratory or skin sensitisation

   Skin sensitisation
   Not classified based on available information.

   Respiratory sensitisation
   Not classified based on available information.

   Germ cell mutagenicity
   Not classified based on available information.

   Components:
   2-phenylpropane-1,3-diyl dicarbamate:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosomal aberration
  Result: negative

Carcinogenicity
Not classified based on available information.

Components:

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)

Reproductive toxicity
Not classified based on available information.

Components:

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 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
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

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 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.

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components consid-
ered to have endocrine disrupting properties according to
REACH Article 57(f) or Commission Delegated regulation
(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at
levels of 0.1% or higher.
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

12.1 Toxicity

Components:

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

12.2 Persistence and degradability

Components:

2-phenylpropane-1,3-diyl dicarbamate:

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

12.3 Bioaccumulative potential

Components:

2-phenylpropane-1,3-diyl dicarbamate:

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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment:
- This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:
Felbamate Suspension Formulation

Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Maritime transport in bulk according to IMO instruments
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) Not applicable
REACH - Candidate List of Substances of Very High Not applicable
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Felbamate Suspension Formulation

Version: 2.3
Revision Date: 09.04.2021
SDS Number: 2368139-00009
Date of last issue: 28.09.2020
Date of first issue: 11.01.2018

Concern for Authorisation (Article 59).
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

Full text of other abbreviations
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Stand-
ardization; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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.