1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Felbamate Solid Formulation

Supplier’s company name, address and phone number
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33nd floor
           Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
E-mail address : EHSSTEWARD@organon.com
Emergency telephone number : 215-631-6999

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements
Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed : Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form combustible dust concentrations in air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-phenylpropane-1,3-diyl dicarba-</td>
<td>25451-15-4</td>
<td>&gt;= 60 - &lt; 70</td>
<td></td>
</tr>
<tr>
<td>mate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
### 5. FIREFIGHTING MEASURES

| Suitable extinguishing media | Water spray  
|                             | Alcohol-resistant foam  
|                             | Carbon dioxide (CO2)  
|                             | Dry chemical  
| Unsuitable extinguishing media | High volume water jet  
| Specific hazards during firefighting | Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
|                             | Do not use a solid water stream as it may scatter and spread fire.  
|                             | Exposure to combustion products may be a hazard to health.  
| Hazardous combustion products | Carbon oxides  
|                             | Nitrogen oxides (NOx)  
| 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.  

### 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.  
|                             | Retain and dispose of contaminated wash water.  
|                             | Local authorities should be advised if significant spillages cannot be contained.  

---

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

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

**In case of eye contact**: If in eyes, rinse well with water. 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.

**Most important symptoms and effects, both acute and delayed**: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

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

**Notes to physician**: Treat symptomatically and supportively.
Methods and materials for containment and cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- 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.

7. HANDLING AND STORAGE

Handling
- **Technical measures:** Static electricity may accumulate and ignite suspended dust causing an explosion.
  - Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

- **Local/Total ventilation:** Use only with adequate ventilation.

- **Advice on safe handling:**
  - Do not breathe dust.
  - Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
  - Minimize dust generation and accumulation.
  - Keep container closed when not in use.
  - Keep away from heat and sources of ignition.
  - Take precautionary measures against static discharges.
  - Take care to prevent spills, waste and minimize release to the environment.

- **Avoidance of contact:** Oxidizing agents

- **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 de-gowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Storage
- **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

- **Packaging material:** Unsuitable material: None known.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-phenylpropane-1,3-diyl di-carbamate</td>
<td>25451-15-4</td>
<td>TWA</td>
<td>400 µg/m$^3$ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m$^3$</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

**Engineering measures**: Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**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: Particulates type
- 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Physical state: powder
- Colour: No data available
- Odour: No data available
- Odour Threshold: No data available
- Melting point/freezing point: No data available
- Boiling point, initial boiling point and boiling range: No data available
- Flammability (solid, gas): May form combustible dust concentrations in air.
- Flammability (liquids): No data available
- Lower explosion limit and upper explosion limit / flammability limit: No data available
- Upper explosion limit / Upper: No data available
SAFETY DATA SHEET

Felbamate Solid Formulation

flammability limit
Lower explosion limit / Lower flammability limit : No data available
Flash point : Not applicable
Decomposition temperature : No data available
pH : No data available
Evaporation rate : Not applicable
Auto-ignition temperature : No data available
Viscosity
Viscosity, kinematic : Not applicable
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : Not applicable
Density and / or relative density
Relative density : No data available
Density : No data available
Relative vapour density : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Dust deflagration index (Kst) : 192 m.b_/s
Minimum ignition energy : 3 - 5 mJ
Particle characteristics
Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
May form combustible dust concentrations in air.
Can react with strong oxidizing agents.
Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

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.

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
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:

2-phenylpropane-1,3-diy 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:

2-phenylpropane-1,3-diy 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

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:

2-phenylpropane-1,3-diyldicarbamate:
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.
SAFETY DATA SHEET
Felbamate Solid Formulation

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: >= 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

12. ECOLOGICAL INFORMATION

Ecotoxicity

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

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:
2-phenylpropane-1,3-diyl dicarbamate:
Stability in water: Hydrolysis: < 10 % (5 d)
### Cellulose:

Biodegradability: Result: Readily biodegradable.

### Bioaccumulative potential

**Components:**

- **2-phenylpropane-1,3-diyl dicarbamate:**
  - Partition coefficient: n-octanol/water: \( \log \text{Pow} = 0.381 \)
  - Mobility in soil: No data available
  - Hazardous to the ozone layer: Not applicable
  - Other adverse effects: No data available

### 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.

### 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.

**National Regulations**

Refer to section 15 for specific national regulation.

### 15. REGULATORY INFORMATION

**Related Regulations**

- **Fire Service Law**: Not applicable to dangerous materials / designated flammables.
Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable
# SAFETY DATA SHEET

## Felbamate Solid 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>2.1</td>
<td>2020/09/28</td>
<td>2332978-00008</td>
<td>2020/03/23</td>
<td>2017/12/13</td>
</tr>
</tbody>
</table>

### Vessel Safety Law
Not regulated as a dangerous good

### Aviation Law
Not regulated as a dangerous good

### Marine Pollution and Sea Disaster Prevention etc Law
- **Bulk transportation**: Not classified as noxious liquid substance
- **Pack transportation**: Not classified as marine pollutant

### Narcotics and Psychotropics Control Act
- **Narcotic or Psychotropic Raw Material (Export / Import Permission)**
  - Not applicable
- **Specific Narcotic or Psychotropic Raw Material (Export / Import permission)**
  - Not applicable

### Waste Disposal and Public Cleansing Law
- **Industrial waste**

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### 16. OTHER INFORMATION

**Further information**

Sources of key data used to compile the Safety Data Sheet:

Date format: yyyy/mm/dd

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **ACGIH / TWA**: 8-hour, time-weighted average

**Abbreviations:**
- AIIIC - 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; 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.

JP / EN