

SAFETY DATA SHEET



Felbamate Suspension Formulation



Version 2.0 Revision Date: 2021/04/09 SDS Number: 2364258-00007 Date of last issue: 2020/09/28
Date of first issue: 2018/01/11

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Felbamate Suspension Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--------------------------------------|------------|-----------------------|
| 2-phenylpropane-1,3-diyl dicarbamate | 25451-15-4 | >= 10 -< 30 |
| Cellulose | 9004-34-6 | < 10 |

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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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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
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.

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 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.

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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 labelled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---------------------------------------|------------|-------------------------------|--|----------|
| 2-phenylpropane-1,3-diyl di-carbamate | 25451-15-4 | TWA | 400 µg/m ³ (OEB 2) | Internal |
| Cellulose | 9004-34-6 | NAB | 10 mg/m ³ | ID OEL |
| | | TWA | 10 mg/m ³ | 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 vapour 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 aerosols.
- Skin and body protection : Work uniform or laboratory coat.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work-

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ing 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.

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 |
| 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 |

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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

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.

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.

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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-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 |
|---------|---|-----|

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| | | |
|-------------------|---|-----------|
| Application Route | : | Ingestion |
| Exposure time | : | 72 weeks |
| Result | : | negative |

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 |

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-diyl dicarbamate:**

| | | |
|---------|---|-----|
| Species | : | Rat |
|---------|---|-----|

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| | |
|-------------------|-------------------------------|
| 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. |

| | |
|-------------------|------------------|
| 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 |

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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 Pow: 0.381

Mobility in soil

No data available

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

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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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Glycerine

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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 : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : yyyy/mm/dd

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Full text of other abbreviations

| | | |
|--------------|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| ID OEL | : | Indonesia. Occupational Exposure Limits |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| ID OEL / NAB | : | Long term exposure limit |

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; 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.

ID / EN