SAFETY DATA SHEET

Felbamate Suspension Formulation

SECTION 1. IDENTIFICATION

Product name: Felbamate Suspension Formulation

Manufacturer or supplier’s details

Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 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>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>2-phenylpropane-1,3-diyl dicarba-</td>
<td>25451-15-4</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>mate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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.

Most important symptoms and effects, both acute and delayed

Protection of first-aiders: No special precautions are necessary for first aid responders.
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Version 2.2   Revision Date: 09/13/2019   SDS Number: 2364239-00006   Date of last issue: 04/24/2019
Date of first issue: 01/11/2018

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting
Hazardous combustion products : Exposure to combustion products may be a hazard to health.
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 fire-fighters : 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 and personal protective equipment recommendations.

Environmental precautions : Discharge into the environment must be avoided.
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 certain local or national requirements.

SECTION 7. HANDLING AND STORAGE
SAFE DATA SHEET

Felbamate Suspension Formulation

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

<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 dicarbamate</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>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
</tbody>
</table>

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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection Material: Chemical-resistant gloves

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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 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.

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

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

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

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

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
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 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)
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

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
IARC  No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA  No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP  No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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 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:**
- **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-diyli 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.

**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
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

Mobility in soil
  No data available

Other adverse effects
  No data available

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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
  Not regulated as a dangerous good
SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>7732-18-5</td>
</tr>
<tr>
<td>D-Glucitol</td>
<td>50-70-4</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
</tr>
<tr>
<td>2-phenylpropane-1,3-diyl dicarbamate</td>
<td>25451-15-4</td>
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<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
</tbody>
</table>

California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
</tbody>
</table>

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

NFPA 704:

<table>
<thead>
<tr>
<th></th>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special hazard</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® IV:

<table>
<thead>
<tr>
<th></th>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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 sub-
Safety Data Sheet

Felbamate Suspension Formulation


Revision Date: 09/13/2019

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.

US / Z8