

SAFETY DATA SHEET



Felbamate Solid Formulation



Version 3.0 Revision Date: 30.09.2023 SDS Number: 2332988-00013 Date of last issue: 04.04.2023
Date of first issue: 13.12.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Felbamate Solid Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054

Telephone : +55 (19) 3758-2000

Emergency telephone : +55 (11) 3173-4931

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Not a hazardous substance or mixture.

GHS label elements in accordance with ABNT NBR 14725 Standard

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards which do not result in classification

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
2-phenylpropane-1,3-diyl di-carbamate	25451-15-4		>= 50 -< 70
Starch, oxidized	65996-62-5		>= 10 -< 20
Cellulose	9004-34-6		>= 5 -< 10

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

SAFETY DATA SHEET



Felbamate Solid Formulation



Version 3.0 Revision Date: 30.09.2023 SDS Number: 2332988-00013 Date of last issue: 04.04.2023
Date of first issue: 13.12.2017

When symptoms persist or in all cases of doubt seek medical advice.

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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : 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 (NO_x)
Metal oxides

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 (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.

Felbamate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.0	30.09.2023	2332988-00013	Date of first issue: 13.12.2017

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 : 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.

SECTION 7. HANDLING AND STORAGE

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.

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.

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

SAFETY DATA SHEET



Felbamate Solid Formulation



Version 3.0 Revision Date: 30.09.2023 SDS Number: 2332988-00013 Date of last issue: 04.04.2023
Date of first issue: 13.12.2017

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
Starch, oxidized	65996-62-5	TWA (inhalable dust)	0,5 mg/m ³	ACGIH
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH

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

Hand protection
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : No data available

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 : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form combustible dust concentrations in air.

SAFETY DATA SHEET



Felbamate Solid Formulation



Version 3.0 Revision Date: 30.09.2023 SDS Number: 2332988-00013 Date of last issue: 04.04.2023
Date of first issue: 13.12.2017

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 : Not applicable

Relative vapor density : Not applicable

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 : 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 size : No data available

SECTION 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Felbamate Solid Formulation

Version 3.0 Revision Date: 30.09.2023 SDS Number: 2332988-00013 Date of last issue: 04.04.2023
Date of first issue: 13.12.2017

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 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:**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

Felbamate Solid Formulation

Version 3.0 Revision Date: 30.09.2023 SDS Number: 2332988-00013 Date of last issue: 04.04.2023
 Date of first issue: 13.12.2017

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
 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 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

Felbamate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.0	30.09.2023	2332988-00013	Date of first issue: 13.12.2017

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:****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.

Felbamate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.0	30.09.2023	2332988-00013	Date of first issue: 13.12.2017

Starch, oxidized:

Species	: Rat
NOAEL	: 22.500 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

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:****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)
--------------------	---------------------------

Felbamate Solid Formulation

Version 3.0 Revision Date: 30.09.2023 SDS Number: 2332988-00013 Date of last issue: 04.04.2023
Date of first issue: 13.12.2017

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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
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

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.

Domestic regulation

ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Felbamate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.0	30.09.2023	2332988-00013	Date of first issue: 13.12.2017

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023
Date format : dd.mm.yyyy

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/>

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 other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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

SAFETY DATA SHEET



Felbamate Solid Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.0	30.09.2023	2332988-00013	Date of first issue: 13.12.2017

es; (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; TECI - Thailand Existing Chemicals Inventory; 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.

BR / Z8