

# **Felbamate Suspension Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.13	30.09.2023	2368135-00014	Date of first issue: 11.01.2018

# **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 th	ne s	substance or mixture and uses advised against
	Use of the Sub- stance/Mixture		Pharmaceutical
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	Organon & Co. 30 Hudson Street, 33nd floor 07302 Jersey City, New Jersey, U.S.A
	Telephone	:	+1-551-430-6000
	E-mail address of person responsible for the SDS	:	EHSSTEWARD@organon.com

## **1.4 Emergency telephone number**

+1-215-631-6999

# **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)

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

## 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.



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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.

# **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-phenylpropane-1,3-diyl dicarba- mate	25451-15-4 247-001-4		>= 10 - < 20

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.



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# **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	n the	e substance or mixture
Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Nitrogen oxides (NOx)
5.3 Advice for firefighters		
Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if nec- essary. Use personal protective equipment.
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances 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 pro- tective 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.	
2 .		For large spills, provide dyking or other appropriate contain-	
		ment to keep material from spreading. If dyked material can	



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		Clean up remain bent. Local or nationa posal of this mat employed in the mine which regu Sections 13 and	re recovered material in appropriate container. hing materials from spill with suitable absor- I regulations may apply to releases and dis- terial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. I 15 of this SDS provide information regarding hational 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	g	
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 as- sessment 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 contami- nated 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, i	inc	luding 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 Gases
7.3 Specific end use(s) Specific use(s)	:	No data available

# 7.1 Precautions for safe handling

# **SECTION 8: Exposure controls/personal protection**

# 8.1 Control parameters

# **Occupational Exposure Limits**

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Comp	onents	CAS-No.	Value type (Form	Control parameters	Basis

Components	CA3-N0.	value type (i onn	Control parameters	Dasis
		of exposure)		
2-phenylpropane- 1,3-diyl dicarba-	25451-15-4	TWA	400 μg/m3 (OEB 2)	Internal
mate				

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

Substance name	End Use	Exposure routes	Potential health ef-	Value
			fects	
Glycerine	Workers	Inhalation	Long-term local ef-	56 mg/m3
			fects	
	Consumers	Ingestion	Long-term systemic	229 mg/kg
			effects	bw/day
	Consumers	Inhalation	Long-term local ef-	33 mg/m3
			fects	-

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

Substance name	Environmental Compartment	Value
Glycerine	Fresh water	0,885 mg/l
	Marine water	0,0885 mg/l
	Intermittent use/release	8,85 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	3,3 mg/kg dry weight (d.w.)
	Marine sediment	0,33 mg/kg dry weight (d.w.)
	Soil	0,141 mg/kg dry weight (d.w.)

## 8.2 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/face 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 Material	:	Chemical-resistant gloves
Skin and body protection Respiratory protection	:	Work uniform or laboratory coat. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Fi	lter type		uld conform to NS EN 14387 culates and organic vapour type (A-P)

# **SECTION 9: Physical and chemical properties**

# 9.1 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	:	No data available
рН	:	No data available
Viscosity Viscosity, kinematic		No data available
	:	NU Uala avaliable
Solubility(ies) Water solubility	:	No data available
	:	
Water solubility Partition coefficient: n-	:	No data available
Water solubility Partition coefficient: n- octanol/water	: : : : : : : : : : : : : : : : : : : :	No data available Not applicable



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Der	nsity	: No data avai	lable			
Relative vapour density Particle characteristics Particle size		: No data available				
		: Not applicab	le			
	er information	: Not explosive	e			
Oxi	dizing properties	: The substan	ce or mixture is not classified as oxidizing.			
Eva	aporation rate	: No data avai	lable			

# **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

Eye contact

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion

## Acute toxicity

Not classified based on available information.

## **Components:**

# 2-phenylpropane-1,3-diyl dicarbamate:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Acute	oral toxicity	: LD50 (Rat): > 5	.000 mg/kg			
		LD50 (Mouse):	> 5.000 mg/kg			
Skin	corrosion/irritation					
Not cl	assified based on ava	ailable information.				
Serio	us eye damage/eye	irritation				
Not cl	assified based on ava	ailable information.				
Resp	iratory or skin sensi	tisation				
-	sensitisation					
Not cl	assified based on ava	ailable information.				
-	iratory sensitisation					
Not cl	assified based on ava	ailable information.				
	cell mutagenicity					
	assified based on ava	ailable information.				
<u>Comp</u>	oonents:					
2-phe	2-phenylpropane-1,3-diyl dicarbamate:					
Genot	toxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative				
		Test Type: Chro Result: negative	omosomal aberration e			
Carci	nogenicity					
Not cl	assified based on ava	ailable information.				
Comp	oonents:					
2-phe	enylpropane-1,3-diyl	dicarbamate:				
Speci		: Mouse				
	ation Route	: Oral				
LOAE	sure time	: 92 weeks : 300 mg/kg body	(weight			
	t Organs	: Liver	y weight			
Speci	es	: Rat				
Applic	ation Route	: Oral				
	sure time	: 104 weeks				
NOAE	EL t Organs	: 30 mg/kg body : Liver, Testes	weight			
Rema		: Benign tumor(s	)			
<b>D</b>						
ĸepro	oductive toxicity					



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Com	ponents:		
2-phe	enylpropane-1,3-diyl		
Effec	ts on fertility		t
Effects on foetal develop- ment		Species: Ra Application Developmer Result: Red	Route: Oral ntal Toxicity: NOAEL: 500 mg/kg body weight uced foetal weight, Embryotoxic effects and ad- s on the offspring were detected only at high ma-
		Species: Ra Application I Developmer Result: Emb	

# 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 NOAEL Application Route Exposure time Target Organs Remarks	:	Rat 100 mg/kg Oral 3 Months Liver May cause damage to organs.
Species NOAEL Application Route Exposure time Target Organs	:	Dog 280 mg/kg Oral 3 Months Liver, Central nervous system
Species NOAEL Application Route Exposure time Target Organs	:	Rat 30 mg/kg Oral 1 yr Liver

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Rema	arks	: May	v cause dam	age to organs.
Species NOAEL Application Route Exposure time Target Organs Remarks		: Ora : 1 yr : Live	ng/kg l er, Central n	ervous system hage 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 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.

#### Experience with human exposure

#### **Components:**

2-phenylpropane-1,3-diyl dicarbamate:					
Ingestion	:	Target Organs: Liver Symptoms: anorexia, Nausea, Vomiting, Headache, Dizzi- ness, 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:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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

## 12.3 Bioaccumulative potential

## **Components:**

## 2-phenylpropane-1,3-diyl dicarbamate:

Partition coefficient: n-: log Pow: 0,381 octanol/water

#### 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:**

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.

If not otherwise specified: Dispose of as unused product.

#### 12.7 Other adverse effects

No data available

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

waste treatment methous		
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. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

## **SECTION 14: Transport information**

14.1 UN number or ID number

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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ADN		: Not regulated as a dangerous good	
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDG	i	: Not regulated as a dangerous good	
ΙΑΤΑ		: Not regulated as a dangerous good	
14.2 UN p	roper shipping name		
ADN		: Not regulated as a dangerous good	
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDG	i	: Not regulated as a dangerous good	
ΙΑΤΑ		: Not regulated as a dangerous good	
14.3 Trans	sport hazard class(e		
ADN		: Not regulated as a dangerous good	
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDG	i	: Not regulated as a dangerous good	
ΙΑΤΑ		: Not regulated as a dangerous good	
14.4 Pack	ing group		
ADN		: Not regulated as a dangerous good	
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDG	i	: Not regulated as a dangerous good	
ΙΑΤΑ	(Cargo)	: Not regulated as a dangerous good	
	(Passenger)	: Not regulated as a dangerous good	
14.5 Envir	onmental hazards	-	
Not re	egulated as a dangero	s good	
-	ial precautions for u	er	
	•	according to IMO instruments	
Rema	ırks	: Not applicable for product as supplied.	

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

REACH - Restrictions on the manufacture, placing on : Not applicable the market and use of certain dangerous substances,

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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REACI	es and articles (Annex 2 H - Candidate List of So rn for Authorisation (Ar	ubstances of Very High	1	:	Not applicable
REACI	H - List of substances s	subject to authorisation		:	Not applicable
	,	9 on substances that c	le-	:	Not applicable
•	ation (EU) 2019/1021 o	n persistent organic po	llu-	:	Not applicable
Regula ment a	ation (ÉC) No 649/2012	of the European Parlia of the European Parlia		:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. 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 other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways: ADR - 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 Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test popula-



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tion; 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; 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

#### 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/

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.

NO / EN