

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Product name: Felbamate Oral Suspension, USP 600 mg/5 mL
Product Code: VY #0336
Synonym(s): Active ingredient - Felbamate; 2-Phenyl-1,3-propanediol dicarbamate

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Felbamate Oral Suspension, USP 600 mg/5 mL is an anticonvulsant drug indicated in the treatment of epilepsy. It is recommended for use only in those patients who respond inadequately to alternative treatments and whose epilepsy is so severe that a substantial risk of aplastic anemia and/or liver failure is deemed acceptable considering the benefits conferred by its use.
Restrictions on use: Felbamate Oral Suspension, USP is not indicated as a first line antiepileptic treatment. Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

1.3 Details of the supplier and of the safety data sheet

Distributed by	Manufactured by
VistaPharm, Inc.	Novitium Pharma LLC
7265 Ulmerton Road	70 Lake Drive
Largo, FL 33771 USA	East Windsor, NJ 08520 USA
+1-727-530-1633	+1-609-469-5920

1.4 Emergency telephone number: In the continental USA: +1-727-530-1633

SECTION 2 - HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

Product definition: Mixture
Classification in accordance with 29 CFR 1910 (OSHA HCS) and Regulation EC No. 1272/2008
 Not a dangerous substance or mixture according to OSHA or to European Union Legislation

2.2 Label elements

Not a dangerous substance or mixture according to GHS

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS

None known

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Concentration	Ingredient	CAS Number	EC Number	Index Number	GHS Classification
600 mg/5 mL	Felbamate	25451-15-4	247-001-4	-----	H317, H334

Inactive ingredients: Non-crystallizing Sorbitol Solution; Microcrystalline Cellulose and Carboxymethylcellulose Sodium; Glycerin; Methylparaben; Propylparaben; Polysorbate 80; Simethicone Emulsion; Saccharin Sodium Monohydrate; Bubblegum Flavor; FD&C Red No.40; FD&C Yellow No.6; Purified Water

There are no additional ingredients present in this product which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

SECTION 4 - FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation: If product mist or vapor causes respiratory irritation or distress, move the exposed person to fresh air immediately. If breathing is difficult or irregular, administer oxygen; if respiratory arrest occurs, start artificial respiration by trained personnel. Get immediate medical attention. If unconscious place in the recovery position and get immediate medical attention. Maintain an open airway. Loosen tight clothing such as a collar tie, belt or waistband. If symptoms persist or if other symptoms develop, seek medical attention.

Eyes: Immediately flush eyes with large amounts of water or saline solution for at least 15 minutes, occasionally lifting the upper and lower lids. Remove contact lenses, if present and easy to do, after first 2 minutes and continue rinsing. If irritation persists, seek medical attention, preferably from an ophthalmologist.

Skin: Rinse skin with water while removing contaminated clothing. Wash the affected area with soap and water. Wash contaminated clothing and shoes before reuse. In the event of any complaints or symptoms, avoid further exposure and seek medical attention.

Ingestion: Rinse mouth with water if the victim is conscious. Remove dentures if present. DO NOT induce vomiting unless directed to do so by

medical personnel. If vomiting occurs, the head should be kept lower than the waist so that vomit does not enter the lungs. Never give anything by mouth to an unconscious or convulsing person. Do not leave the victim unattended. If the victim is unconscious, place in the recovery position and immediately contact a POISON CONTROL CENTER or doctor. Seek medical attention if adverse health effects persist or are severe.

4.2 Most important symptoms and effects, both acute and delayed

Potential health symptoms and effects

Eyes: May cause eye irritation.

Skin: May cause skin irritation. May cause an allergic skin reaction in susceptible individuals. Symptoms include rash, itching and discomfort. Prolonged and repeated contact with unprotected skin may cause dermatitis.

Inhalation: This product is not expected to be an inhalation hazard when used as directed. Inhalation of mist may cause allergy or asthma symptoms or breathing difficulties in susceptible individuals.

Ingestion: May cause gastrointestinal irritation with nausea, vomiting, abdominal pain and diarrhea or constipation. May cause dizziness, drowsiness, headache, insomnia, hiccups, nervousness, tiredness, ear pain and blurred vision. May cause changes in weight, anorexia and change in sense of taste. May cause rhinitis, itching, skin rash and acne. Refer to product insert for complete side effect data.

Chronic: Refer to product insert for full details of chronic effects.

4.3 Indication of any immediate medical attention and special treatment needed

Advice to doctor and hospital personnel

Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

SECTION 5 - FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable methods of extinction: Use extinguishing media suitable for the surrounding fire.

Unsuitable methods of extinction: None known

5.2 Special hazards arising from the substance or mixture

During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent or may be delayed. Obtain medical attention.

Explosion hazards: This product is not considered to be an explosion hazard.

5.3 Advice to firefighters

Full protective equipment including self-contained breathing apparatus should be used. If possible, firefighters should control runoff water to prevent environmental contamination.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Evacuate non-essential personnel. Wear appropriate protective clothing and equipment designated in Section 8.2. Ventilate the area. Remove all sources of ignition. No smoking. Clean up spills immediately. Spills create slip hazards.

6.2 Environmental precautions

Avoid dispersal of spilled material or runoff and prevent contact with soil and entry into drains, sewers or waterways.

6.3 Methods and materials for containment and cleaning up

Cover drains and contain spill. Small spills can be wiped up with absorbent material (e.g. cloth, fleece). Cover larger spills with inert absorbent. Do not use combustible material such as sawdust. Collect material and place into an approved, labeled container for proper disposal. Observe possible material restrictions (Sections 7.2 and 10.5). Dispose of material via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations. Clean contaminated area with soap and water.

6.4 Reference to other sections

See Section 13 for additional waste treatment information.

SECTION 7 - HANDLING AND STORAGE

7.1 Precautions for safe handling

Observe all label precautions. Wear all appropriate personal protective equipment specified in Section 8.2. Do not get in eyes or on skin or clothing. No smoking. If normal use of material presents a respiratory hazard, use only adequate ventilation or wear an appropriate respirator.

Advice on protection against fire and explosion

Product does not present a fire or explosion hazard.

7.2 Conditions for safe storage, including any incompatibilities

Store at controlled room temperature between 20 - 25 °C (68 - 77 °F); excursions permitted between 15 - 30 °C (59 - 86 °F). Store in a dry, well-ventilated area away from incompatible materials (see Section 10.5), food and drink. Keep container tightly closed when not in use. Protect containers from physical damage. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Containers of

this material are hazardous when empty as they contain product residue. Use appropriate containment to avoid environmental contamination. Ventilate closed areas. Keep locked up and out of reach of children.

7.3 Specific end uses

Apart from the uses mentioned in Section 1.2, no other specific uses are stipulated.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limit values

Contains no substances with occupational exposure values.

8.2 Exposure controls

Engineering measures: Use adequate ventilation. Local exhaust is preferable. Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Individual protection measures: Not normally required. Wear protective clothing to prevent repeated or prolonged contact with product. Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled.

Hygiene measures: Facilities storing or using this material should be equipped with an eyewash station and safety shower. Change contaminated clothing. Wash hands and forearms thoroughly after use, before eating, drinking, smoking or using the lavatory.

Eye/face protection: None normally required. If there is a danger of splashing wear safety glasses with unperforated side shields during use.

Hand protection: Wear Nitrile rubber gloves or those recommended by glove supplier for protection against materials in Section 3. Breakthrough time of selected gloves must be greater than the intended use period.

Other protective equipment: Not normally needed. Wear protective clothing and protective boots if the situation requires.

Respiratory protection: No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to vapor/fume at levels exceeding the exposure limits.

Environmental exposure controls: Do not empty into drains.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Pink colored, homogeneous suspension
Odor	Bubblegum
Odor Threshold	No data available
Molecular Weight	238.24 g/mol (Felbamate)
Chemical Formula	C ₁₁ H ₁₄ N ₂ O ₄ (Felbamate)
pH (1% aqueous solution)	4.5 - 6.0
Freezing/Melting Point	No data available
Boiling Point Range	No data available
Evaporation Rate	No data available
Flammability (solid, gas)	Not applicable
Flash Point	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Lower Explosive Limit (LEL)	No data available
Upper Explosive Limit (UEL)	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	No data available
Density	1.1 - 1.2 g/mL
Viscosity	100 - 350 cPs
Solubility in Water	Slightly soluble
Partition Coefficient (n-octanol/water)	No data available
Oxidizing Properties	Not applicable
Explosive Properties	Not applicable
Volatiles by Weight @ 21 °C	No data available

9.2 Other Data

No data available

SECTION 10 - STABILITY AND REACTIVITY

10.1 Reactivity

No special reactivity has been reported during normal conditions of handling and use.

10.2 Chemical Stability

This material is stable under recommended storage and handling conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4 Conditions to avoid

Avoid temperature extremes and contact with incompatible materials.

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Thermal decomposition products may include oxides of carbon and nitrogen oxides.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute oral toxicity

LD₅₀, rat: > 5,000 mg/kg (Felbamate)

May be harmful if swallowed in large quantities.

Acute inhalation toxicity

Expected to have low acute inhalation toxicity.

Acute dermal toxicity

Expected to have low acute dermal toxicity.

Skin irritation

May cause skin irritation.

Eye irritation

May cause eye irritation.

Sensitization

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Genotoxicity in vitro

No data available

Mutagenicity

No data available

Specific organ toxicity - single exposure

No data available

Specific organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Further information

In humans, there is an increased incidence of aplastic anemia and liver toxicity associated with the use of Felbamate (CAS #25451-15-4).

Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12 - ECOLOGICAL INFORMATION

12.1 Toxicity

No data is available regarding the environmental toxicity of this product. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulation potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other effects

Additional ecological information

Do not allow material to enter surface waters, wastewater or soil.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

SECTION 13 - DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

The generation of waste should be avoided or minimized whenever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

RCRA F-Series: No listings above the reportable threshold (de minimis)

RCRA U-Series: No listings above the reportable threshold (de minimis)

SECTION 14 - TRANSPORT INFORMATION

Note: Transportation information provided is for reference only. Customer is urged to consult 49 CFR 100 - 177, IMDG, IATA, EC, United Nations TDG and WHMIS (Canada) TDG information manuals for detailed regulations and exceptions covering specific container sizes, packaging materials and methods of shipping.

NOT REGULATED FOR TRANSPORT (NOT DANGEROUS GOODS)

SECTION 15 - REGULATORY INFORMATION

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

U. S. Federal Regulations

OSHA Hazard Communication Standard: This material is not classified as hazardous in accordance with OSHA 29 CFR 1910-1200.

Toxic Substance Control Act (TSCA) Inventory: Felbamate (CAS #2545-15-4) is not listed on the Toxic Substance Control Act (TSCA) Inventory as it is intended for use in applications regulated by the Food and Drug Administration in the United States. It can only be used for TSCS exempt purposes such as R&D or drug use. It is not subject to TSCA 12(b) Export Notification.

Drug Enforcement Administration (DEA) List 2, Essential Chemicals (21 CFR 1310.02(b)) and 1310.4(f)(2)) and Chemical Code Number No listings

Drug Enforcement Administration (DEA) Lists 1 & 2, Exempt Chemical Mixtures (21 CFR 1310.12(c)) and Code Number: No listings

Superfund Amendments and Reauthorization Act (SARA)

SARA Section 311/312 Hazard Categories: None known

SARA 313 Information: None of the chemicals in this product exceed the threshold (de minimis) reporting levels established by Section 313 of the Emergency Planning and Community Right-to Know Act of 1986.

SARA 302/304 Extremely Hazardous Substance: None of the components of this product exceed the threshold (de minimis) reporting levels established by these sections of Title III of SARA.

SARA 302/304 Emergency Planning & Notification: None of the components of this product exceed the threshold (de minimis) reporting levels established by these sections of Title III of SARA.

Comprehensive Response Compensation and Liability Act (CERCLA): No components of the product exceed the threshold (de minimis) reporting levels for hazardous wastes established by CERCLA.

Clean Air Act (CAA)

This product does not contain Hazardous Air Pollutants (HAPs) designated in CAA Section 112 (b).

This product does not contain Class 1 ozone depleters.

This product does not contain Class 2 ozone depleters.

Clean Water Act (CWA)

This product does not contain Hazardous Substances listed under the CWA.

This product does not contain Priority Pollutants.

This product does not contain Toxic pollutants.

U.S. State Regulations

California Prop 65, Safe Drinking Water and Toxic Enforcement Act of 1986

This product contains no chemical(s) known to the state of California to cause cancer birth defects or reproductive harm in concentrations that exceed the threshold (de minimis) reporting levels established under Proposition 65.

Other U.S. State Inventories

None of the components of this product exceed the threshold (de minimis) reporting level of any the State Hazardous Substance Inventories, Right-to-Know lists and/or Air Quality/Air Pollutants lists.

Canada

WHMIS Hazard Classification: Uncontrolled product according to WHMIS classification criteria

Canadian National Pollutant Release Inventory (NPRI): None of the chemicals in this product are listed on the NPRI.

European Economic Community

WGK, Germany (Water danger/protection): No data available

Global Chemical Inventory Lists

Country	Inventory Name	Listed*
Canada	Domestic Substance List (DSL)	No
Canada	Non-Domestic Substance List (NDSL)	No
Europe	Inventory of New and Existing Chemicals (EINECS)	Yes
United States	Toxic Substance Control Act (TSCA)	No
Australia	Australian Inventory of Chemical Substances (AICS)	No
New Zealand	New Zealand Inventory of Chemicals (NZIoC)	No
China	Inventory of Existing Chemical Substances in China	No
Japan	Inventory of Existing and New Chemical Substances	No
Korea	Existing Chemicals List (KECI)	No
Philippines	Philippines Inventory of Chemicals and Chemical	No

*Yes - All components of this product are in compliance with the inventory requirements administered by the governing country.
No - One or more components of this product are not on the inventory or are exempt from listing.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16 - OTHER INFORMATION

Hazardous Material Information System (HMIS)

HEALTH	*	0
FLAMMABILITY		0
PHYSICAL HAZARD		0
PERSONAL PROTECTION		

HMIS Hazard Rating Legend

0 = Minimal 1 = Slight 2 = Moderate

3 = Serious 4 = Severe

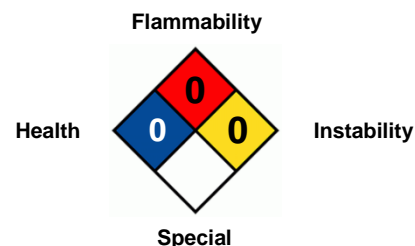
* = Chronic Health Hazard

NFPA Hazard Rating Legend

0 = Insignificant 1 = Slight 2 = Moderate

3 = High 4 = Extreme

National Fire Protection Association (NFPA)



Full text of GHS Hazard Phrases referenced in Section 3 (not covered in Section 2)

H317 – May cause an allergic skin reaction

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

The information herein is given in good faith and is believed to be accurate and correct; however, no warranty, expressed or implied, is made.

VistaPharm, Inc. assumes no responsibility for personal injury or property damage that may arise from the use of this material since the conditions of handling and use are beyond our control. It is the responsibility of the user to comply with all Federal, State and local laws and regulations regarding use of this product. Vendees or users assume all risks associated with the use of this material.

Revision date: 07 May 2019, Version 2

Superseded SDS: 26 September 2018, Version 1

<end of document>