Felbamate

sc-203579

Material Safety Data Sheet

Hazard Alert Code Key: EXTREME HIGH MODERATE LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Felbamate

STATEMENT OF HAZARDOUS NATURE

NFPA

SUPPLIER
Santa Cruz Biotechnology, Inc.
2145 Delaware Avenue
Santa Cruz, California 95060
800.457.3801 or 831.457.3800

EMERGENCY:
ChemWatch
Within the US & Canada: 877-715-9305
Outside the US & Canada: +1-800-2436-2255
(1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS
C11-H14-N2-O4, "carbamic acid, 2-phenyltrimethylene ester", "1, 3-propanediol, 2-phenyl- dicarbamate", "2-phenyl-1, 3-propanediol dicarbamate", Felbamato, Felbamy, Felbatol, Taloxa, W-554, "antiepileptic/anticonvulsant", "GABA agonist", "glutamate/kainate antagonist", "meprobamate analogue"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Toxicity</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Body Contact</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Reactivity</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Chronic</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Canadian WHMIS Symbols

1 of 8
ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- Antiepileptic drugs (AEDs) act as anticonvulsants and increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Persons exposed to AEDs for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior (such as anxiety, agitation, hostility, pressured/rapid speech). The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5-100 years) in the clinical trials analyzed.
- The relative risk for suicidal thoughts or behavior was higher in clinical trials for epilepsy than in clinical trials for psychiatric or other conditions, but the absolute risk differences were similar for the epilepsy and psychiatric indications.
- Exposure to the anxiolytic sedatives, hypnotics and neuroleptics may produce drowsiness or sedation. Depression of the central nervous system may occur early.

<p>
- The material may mimic the actions of the major inhibitory neurotransmitter of the brain, GABA, (gamma-aminobutyric acid) in inhibiting the electrical activity of certain elements of the nervous system. GABA is a putative amino-acid, produced within certain neurones (presynaptic cells) and is released into the synapse, between neurones, on the arrival of an action potential; GABA then interacts with post-synaptic neurones, slowing their rate of firing.

- Certain GABA congeners may produce lightheadedness, ataxia, mood elevation and muscle incoordination. Side-effects of uptake of GABA analogues and congeners (such as the isoxazole derivative, muscimol, isolated from hallucinogenic mushrooms), by neurones, may include dizziness, ataxia, euphoria, muscle twitches, and initial psychic stimulations followed by dream-filled sleep. More severe ingestions may produce visual disturbances, fever, confusion, myoclonus, mydriasis, seizures and coma. Residual headache may persist for several days. The congener muscimol is structurally related to GABA, crosses the blood-brain barrier easily, in contrast to GABA, and inhibits the firing of some central neurones. GABA, when introduced directly to the brain by injection (i.e. intrathecally), produces the same effect and similar outcomes to those produced by muscimol.

- Another amino-acid, with a similar structure to both GABA and muscimol, is isotonic acid (also derived from mushrooms). Effects of ingestion are similar to those produced by muscimol. Ibotoxin acid, however, binds to a different receptor, NMDA, which is normally activated by the putative neurotransmitter glutamic acid but now is inhibited by the action of ibotenic acid. NMDA receptors, in contrast to GABA receptors, when activated, normally cause neurones to fire. Systemic administration of ibotenic acid and muscimol to laboratory animals produces central inhibition of motor activity with little change to peripheral autonomic activity. Both compounds induce EEG changes in cats, rabbits and rats and thus within the central nervous system both compounds behave as false inhibitory neurotransmitters.

- GABA and its congeners inhibit the excitation of cells, of neurological origin, by allowing anions, such as chloride, to enter the cell thus altering the electric potential of the cell. The GABA receptor acts as a gateway for influx of chloride ion.

- One subtype of receptor for GABA, the GABA-A receptor also contains binding sites for anxiolytic barbiturates, benzodiazepines, neurosteroids and, probably, ethanol. These anxiolytic groups potentiate the function of the chloride channels linked to the receptor. The whole receptor complex can be formed only by the interaction of several individual subunits, each of which is a membrane-spanning protein. Several different types of subunit have been identified and named the alpha-, beta-, and delta- subunits. The receptor may be made from any of up to five possible combinations of these subunits so that the number of possible subtypes of GABA-A receptor is huge and may, in part, explain their variable response to each anxiolytic agent. However, receptors made from any combination of two or three subunit types express much of the function of the native receptor.

EYE

- Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.

SKIN

- Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
- There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
- Photosensitization designates an abnormal adverse reaction to ultraviolet (UV) and/or visible radiation and is used to describes phototoxic reactions (those having a non-immunological basis), photallergic reactions (those having an immunological basis) and other, as yet, unexplained reactions of the skin and eyes to sunlight.

- This material is a photosensitizer. Certain individuals working with this substance may show allergic reaction of the skin under sunlight.

INHALED
The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models). Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

The anxiolytic sedatives, hypnotics and neuroleptics may produce dependence in susceptible individuals; dependency is characterized by a strong need to continue taking the drug; a tendency to increase the dose, a psychic dependence on the effects of the drug, and a physical dependence on the effects of the drug for the maintenance of homeostasis, with a characteristic abstinence syndrome on withdrawal. Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

Exposure to small quantities may induce hypersensitivity reactions characterized by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic edema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur.

Repeated ingestion of the congener meprobamate produces decreased muscle tone and weakness progressing to paralysis, fast EEG activity, paresthesias, modest hyperalgesia, nausea, vomiting, abdominal pain, diarrhoea, loss of visual acuity, palpitations and transient ECG changes. Sensitisation or idiosyncratic reactions to meprobamate include serum sickness. More severe reactions may include hyperpyrexia, chills, oliguria, anuria, stomatitis, proctitis and various fatal skin reactions and anaphylaxis. An association with congenital malformations has been suggested following meprobamate use during the first trimester of pregnancy. Reproductive effects have been reported in animals.

### Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>NAME</th>
<th>CAS RN</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>felbamate</td>
<td>25451-15-4</td>
<td>&gt;98</td>
</tr>
</tbody>
</table>

### Section 4 - FIRST AID MEASURES

**SWALLOWED**

- If swallowed do NOT induce vomiting. - If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

**EYE**

- If this product comes in contact with the eyes: - Wash out immediately with fresh running water. - Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

**SKIN**

- If skin contact occurs: - Immediately remove all contaminated clothing, including footwear - Flush skin and hair with running water (and soap if available).

**INHALED**

- If dust is inhaled, remove from contaminated area. - Encourage patient to blow nose to ensure clear passage of breathing. - If irritation or discomfort persists seek medical attention.

### NOTES TO PHYSICIAN

- For anticonvulsants:
  It is recommended that the physician withdraw the drug slowly on the appearance of unusual depression, aggressiveness, or other behavioral alterations.

As with other anticonvulsants, it is important to proceed slowly when increasing or decreasing dosage, as well as when adding or eliminating other medication. Abrupt withdrawal of anticonvulsant medication may precipitate absence (petit mal) status. Following recent ingestion or overdose of anxiolytic sedatives, hypnotics and neuroleptics, the stomach may be emptied by gastric lavage and aspiration. Patients should be managed with intensive symptomatic and supportive therapy with particular attention being paid to the maintenance of cardiovascular, respiratory and renal functions and to the maintenance of electrolyte balance.

### Section 5 - FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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<tbody>
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<td>Vapour Pressure (mmHG)</td>
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<td>Upper Explosive Limit (%)</td>
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</tr>
<tr>
<td>Specific Gravity (water=1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Lower Explosive Limit (%)</td>
<td>Not available</td>
</tr>
</tbody>
</table>
EXTINGUISHING MEDIA
- Foam.
- Dry chemical powder.

FIRE FIGHTING
- Alert Emergency Responders and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS
- Combustible solid which burns but propagates flame with difficulty.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
- Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.
- May emit poisonous fumes.
- May emit corrosive fumes.

FIRE INCOMPATIBILITY
- Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION
- Glasses: Chemical goggles.
- Gloves:
- Respirator: Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS
- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

MAJOR SPILLS
- CAUTION: Advise personnel in area.
- Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING
- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS
- Glass container.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS
- Store in original containers.
- Keep containers securely sealed.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS
The following materials had no OELs on our records
- felbamate: CAS:25451-15-4

PERSONAL PROTECTION
RESPIRATOR
Particulate
Consult your EHS staff for recommendations

EYE
- When handling very small quantities of the material eye protection may not be required.
For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:
  · Chemical goggles
  · Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
  · Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET
- Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
  · frequency and duration of contact,
  · chemical resistance of glove material,
  · glove thickness and
  · dexterity
Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).
  · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
  · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
  · Contaminated gloves should be replaced.
Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
  · Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
  · Double gloving should be considered.
  · PVC gloves.
  · Protective shoe covers.
  · Head covering.
Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.
  · polychloroprene
  · nitrile rubber
  · butyl rubber
  · fluoroelastomer
  · polyvinyl chloride
Gloves should be examined for wear and/ or degradation constantly.

OTHER
- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit.

ENGINEERING CONTROLS
- Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.
HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES
Solid.
Does not mix with water.

<table>
<thead>
<tr>
<th>State</th>
<th>Divided solid</th>
<th>Molecular Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>238.2</td>
</tr>
</tbody>
</table>
Melting Range (°F) 303.8- 305.6  Viscosity Not Applicable
Boiling Range (°F) Not available  Solubility in water (g/L) Partly miscible
Flash Point (°F) Not available  pH (1% solution) Not Applicable
Decomposition Temp (°F) Not available  pH (as supplied) Not applicable
Autoignition Temp (°F) Not available  Vapour Pressure (mmHG) Negligible
Upper Explosive Limit (%) Not available  Specific Gravity (water=1) Not available
Lower Explosive Limit (%) Not available  Relative Vapor Density (air=1) Not Applicable
Volatile Component (%vol) Negligible  Evaporation Rate Not Applicable

**APPEARANCE**
White, odourless powder; does not mix well with water. Soluble in DMSO, 1-methyl-2-pyrrolidinone and DMF.

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**Section 10 - CHEMICAL STABILITY**

**CONDITIONS CONTRIBUTING TO INSTABILITY**
- Presence of incompatible materials.
- Product is considered stable.

**STORAGE INCOMPATIBILITY**
- Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

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**Section 11 - TOXICOLOGICAL INFORMATION**

**FELBAMATE**

**TOXICITY AND IRRITATION**

**FELBAMATE:**
- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

<table>
<thead>
<tr>
<th>TOXICITY</th>
<th>IRRITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral (rat) LD50: &gt;5000 mg/kg</td>
<td>Nil Reported</td>
</tr>
<tr>
<td>Oral (mouse) LD50: &gt;5000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Intraperitoneal (mouse) LD50: 4000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Oral (Human) TDL0: 140 mg/kg</td>
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</tr>
<tr>
<td>Oral (Human) TDL0: 1296 mg/kg</td>
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<tr>
<td>Oral (Human) TDL0: 24 mg/kg</td>
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<tr>
<td>Intraperitoneal (Rat) LD50: 1625 mg/kg</td>
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<tr>
<td>Intraperitoneal (Mouse) LD50: 659 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Oral (Human) TDL0: 12 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Oral (Mouse) TDL0: 35 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Oral (Mouse) TDL0: 600 mg/kg</td>
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</tr>
</tbody>
</table>

- Reports suggest an association between the use of anticonvulsant drugs by women with epilepsy and an elevated incidence of birth defects in children born to these women. Data are more extensive with respect to phenytoin and phenobarbital, but these are also the most commonly prescribed anticonvulsants; less systematic or anecdotal reports suggest a possible similar association with the use of all known anticonvulsant drugs.

The frequency of major malformations, growth retardation, and hypoplasia of the midface and fingers, known as "anticonvulsant embryopathy", is increased in infants exposed to anticonvulsant drugs in utero. However, whether the abnormalities are caused by the maternal epilepsy itself or by exposure to anticonvulsant drugs is not known. The reports suggesting an elevated incidence of birth defects in children of drug-treated epileptic women cannot be regarded as adequate to prove a definite cause and effect relationship. There are intrinsic methodologic problems in obtaining adequate data on drug teratogenicity in humans; the possibility also exists that other factors, eg, genetic factors or the epileptic condition itself, may be more important than drug therapy in leading to birth defects. The great majority of mothers on anticonvulsant medication deliver normal infants.

At least one study has shown a distinctive pattern of physical abnormalities in infants of mothers with epilepsy is associated with the use of anticonvulsant drugs during pregnancy, rather than with epilepsy itself (L.B. Holmes etal New England Jnl of Med, 344: 1132-1138; 2001).

It is important to note that anticonvulsant drugs should not be discontinued in patients in whom the drug is administered to prevent major seizures because of the strong possibility of precipitating status epilepticus with attendant hypoxia and threat to life. In individual cases where the severity and frequency of the seizure disorder are such that the removal of medication does not pose a serious threat to the patient, discontinuation of the drug may be considered prior to and during pregnancy, although it cannot be said with any confidence that even minor seizures do not pose some hazard to the developing embryo or foetus.

Reproductive dysfunction in epilepsy is attributed to the seizures themselves and also to antiepileptic drugs (AEDs), which affect steroid production, binding, and metabolism. In turn, neuroactive steroids may influence neuronal excitability. A previous study in this cohort of
consecutive women with epilepsy showed that patients with more frequent seizures had higher cortisol and lower dehydroepiandrosterone sulfate levels than those with rare or absent seizures. Actual hormone titers were not significantly correlated with seizure frequency scores (SFS) rather these hormonal changes were explained by AED treatments, mainly when enzyme-inducing AEDs (EIAED) polytherapies were given.

**Section 12 - ECOLOGICAL INFORMATION**

*No data*

**Ecotoxicity**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Persistence: Water/Soil</th>
<th>Persistence: Air</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
</tr>
</thead>
<tbody>
<tr>
<td>felbamate</td>
<td>HIGH</td>
<td></td>
<td></td>
<td>MED</td>
</tr>
</tbody>
</table>

**Section 13 - DISPOSAL CONSIDERATIONS**

**Disposal Instructions**

All waste must be handled in accordance with local, state and federal regulations. Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

**Section 14 - TRANSPORTATION INFORMATION**

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

**Section 15 - REGULATORY INFORMATION**

No data for felbamate (CAS: , 25451-15-4)

**Section 16 - OTHER INFORMATION**

**LIMITED EVIDENCE**

- Skin contact and/or ingestion may produce health damage*.
- Cumulative effects may result following exposure*.
- May produce skin discomfort*.

* (limited evidence).

Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no representations and assumes no liability for any direct, incidental or consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references. A list of reference resources used to assist the committee may be found at: www.chemwatch.net/references.

The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.