Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**PRODUCT NAME**
Vigabatrin

**STATEMENT OF HAZARDOUS NATURE**

**NFPA**

**SUPPLIER**
Company: Santa Cruz Biotechnology, Inc.
Address:
2145 Delaware Ave
Santa Cruz, CA 95060
Telephone: 800.457.3801 or 831.457.3800
Emergency Tel: CHEMWATCH: From within the US and Canada: 877-715-9305
Emergency Tel: From outside the US and Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

**PRODUCT USE**
Antiepileptic agent. An irreversible inhibitor of GABA-transaminase, the enzyme responsible for the catabolism of the neurotransmitter, GABA.

**SYNONYMS**
C6-H11-N-O2, C6-H11-N-O2, "5-hexenoic acid, 4-amino-", "5-hexenoic acid, 4-amino-", "4-amino-5-hexenoic acid", "4-amino-5-hexenoic acid", "4-amino-hex-5-enoic acid", "4-amino-hex-5-enoic acid", "gamma-vinyl GABA", "gamma-vinyl aminobutyric acid", GVG, "MDL 71754", "RMI 71754", Sabril, antiepileptic

Section 2 - HAZARDS IDENTIFICATION

**EMERGENCY OVERVIEW**
**RISK**
Possible risk of harm to the unborn child.
Irritating to eyes, respiratory system and skin.

**POTENTIAL HEALTH EFFECTS**

**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 analysed.

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.

**EYE**
- This material can cause eye irritation and damage in some persons.

**SKIN**
- This material can cause inflammation of the skin on contact in some persons.
- The material may accentuate any pre-existing dermatitis condition.
- Skin contact is not thought to have harmful health effects, however the material may still produce health damage following entry through wounds, lesions or abrasions.
- 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.

**INHALED**
- The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
- 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**
- Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.
- Results in experiments suggest that this material may cause disorders in the development of the embryo or fetus, even when no signs of poisoning show in the mother.
- Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.
- 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. Prime symptom is breathlessness; lung shadows show on X-ray.

### Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

#### HAZARD RATINGS

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

**NAME**

<table>
<thead>
<tr>
<th>CAS RN</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>60643-86-9</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.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

#### 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.
  - If pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

#### SKIN
- If skin contact occurs:
  - Immediately remove all contaminated clothing, including footwear
  - Flush skin and hair with running water (and soap if available).
Seek medical attention in event of irritation.

**INHALED**
- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
- Transport to hospital, or doctor, without delay.

**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. Treat symptomatically.

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**Section 5 - FIRE FIGHTING MEASURES**

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<tr>
<th>Property</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td><strong>Vapour Pressure (mmHG):</strong></td>
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<tr>
<td><strong>Upper Explosive Limit (%):</strong></td>
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</tr>
<tr>
<td><strong>Specific Gravity (water=1):</strong></td>
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</tr>
<tr>
<td><strong>Lower Explosive Limit (%):</strong></td>
<td>Not available</td>
</tr>
</tbody>
</table>

**EXTINGUISHING MEDIA**
- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

**FIRE FIGHTING**
- Alert Emergency Responders and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water course.
- Use water delivered as a fine spray to control fire and cool adjacent area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

**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.
- Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.
- 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

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**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

• Moderate hazard.
• CAUTION: Advise personnel in area.
• Alert Emergency Responders and tell them location and nature of hazard.
• Control personal contact by wearing protective clothing.
• Prevent, by any means available, spillage from entering drains or water courses.
• Recover product wherever possible.
• IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.
• ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.
• If contamination of drains or waterways occurs, advise emergency services.

ACUTE EXPOSURE GUIDELINE LEVELS (AEGL) (in ppm)

AEGL 1: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.

AEGL 2: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.

AEGL 3: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

• Avoid all personal contact, including inhalation.
• Wear protective clothing when risk of exposure occurs.
• Use in a well-ventilated area.
• Prevent concentration in hollows and sumps.
• DO NOT enter confined spaces until atmosphere has been checked.
• DO NOT allow material to contact humans, exposed food or food utensils.
• Avoid contact with incompatible materials.
• When handling, DO NOT eat, drink or smoke.
• Keep containers securely sealed when not in use.
• Avoid physical damage to containers.
• Always wash hands with soap and water after handling.
• Work clothes should be laundered separately.
• Launder contaminated clothing before re-use.
• Use good occupational work practice.
• Observe manufacturer's storing and handling recommendations.
• Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

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.
• Store in a cool, dry, well-ventilated area.
• Store away from incompatible materials and foodstuff containers.
• Protect containers against physical damage and check regularly for leaks.
• Observe manufacturer's storing and handling recommendations.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS
Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

<table>
<thead>
<tr>
<th>Source</th>
<th>Material</th>
<th>TWA ppm</th>
<th>TWA mg/m³</th>
<th>STEL ppm</th>
<th>STEL mg/m³</th>
<th>Peak ppm</th>
<th>Peak mg/m³</th>
<th>TWA F/CC</th>
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<td>vigabatrin (Inert or Nuisance Dust: (d) Total dust)</td>
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<tr>
<td>US OSHA Permissible Exposure Levels (PELs) - Table Z3</td>
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<tr>
<td>US - Hawaii Air Contaminant Limits</td>
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<tr>
<td>US - Oregon Permissible Exposure Limits (Z3)</td>
<td>vigabatrin (Inert or Nuisance Dust: (d) Respirable fraction)</td>
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</tbody>
</table>

MATERIAL DATA

VIGABATRIN:
- It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.

Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers’ responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach, typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life. However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.

OSHA (USA) concluded that exposure to sensory irritants can:
- cause inflammation
- cause increased susceptibility to other irritants and infectious agents
- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

Airborne particulate or vapor must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

PERSONAL PROTECTION
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 irritation 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
- fluorocautchouc
- 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
- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory . These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

### RESPIRATOR

<table>
<thead>
<tr>
<th>Protection Factor</th>
<th>Half-Face Respirator</th>
<th>Full-Face Respirator</th>
<th>Powered Air Respirator</th>
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<tr>
<td>10 x PEL</td>
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<td>-</td>
<td>PAPR-P1</td>
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<td>Air-line*</td>
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Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid. Mixes with water.

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<th>State</th>
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<td>Flash Point (°F)</td>
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<td>pH (1% solution)</td>
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<td>pH (as supplied)</td>
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<td>Not available.</td>
<td>Relative Vapor Density (air=1)</td>
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</table>

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.

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.

Use appropriate NIOSH-certified respirator based on informed professional judgement. In conditions where no reasonable estimate of exposure can be made, assume the exposure is in a concentration IDLH and use NIOSH-certified full face pressure demand SCBA with a minimum service life of 30 minutes, or a combination full facepiece pressure demand SAR with auxiliary self-contained air supply. Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

Explanation of Respirator Codes:

- Negative pressure demand
- Continuous flow

PAPR Powered Air Purifying Respirator (positive pressure) cartridge.

- Type A for use against certain organic gases and vapors.
- Type AX for use against low boiling point organic compounds (less than 65°C).
- Type B for use against certain inorganic gases and other acid gases and vapors.
- Type E for use against sulfur dioxide and other acid gases and vapors.
- Type K for use against ammonia and organic ammonia derivatives

Class 1 low to medium absorption capacity filters.
Class 2 medium absorption capacity filters.
Class 3 high absorption capacity filters.

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For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant: Air Speed:
- solvent, vapors, etc. evaporating from tank (in still air) 0.25-0.5 m/s (50-100 f/min.)
- aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation) 0.5-1 m/s (100-200 f/min.)
- direct spray, drum filling, conveyor loading, crusher dusts, gas discharge (active generation into zone of rapid air motion) 1-2.5 m/s (200-500 f/min.)

Within each range the appropriate value depends on:
1: Room air currents minimal or favourable to capture
2: Contaminants of low toxicity or of nuisance value only.
3: Intermittent, low production.
4: Large hood or large air mass in motion
1: Disturbing room air currents
2: Contaminants of high toxicity
3: High production, heavy use
4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.
vigabatrin

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY
- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerization will not occur.

STORAGE INCOMPATIBILITY
- Avoid reaction with oxidizing agents.

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

Section 11 - TOXICOLOGICAL INFORMATION

TOXICITY AND IRRITATION
- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY
- Oral (rat) LD50: 3000 mg/kg
- Oral (mouse) LD50: 3000 mg/kg

IRRITATION
- Intraperitoneal (mouse) LD50: >2500 mg/kg

Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

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.

Changes in surface EEG, hallucinations, toxic psychosis, ptosis, somnolence, degenerative changes in the brain, reproductive tumours, retinal changes (pigmented deposits, retinitis) recorded.

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:

VIGABATRIN
- DO NOT discharge into sewer or waterways.

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>vigabatrin</td>
<td>LOW</td>
<td>LOW</td>
<td>LOW</td>
<td>HIGH</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.
• Dispose of by: Burial in a licensed land-fill or Incineration in a licensed apparatus (after admixture with suitable combustible material)
• Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

vigabatrin (CAS: 60643-86-9) is found on the following regulatory lists:
"US - Hawaii Air Contaminant Limits","US - Oregon Permissible Exposure Limits (Z3)","US OSHA Permissible Exposure Levels (PELs) - Table Z3"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE
■ Ingestion may produce health damage*.
■ Cumulative effects may result following exposure*.
* (limited evidence).

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Classification of the mixture 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.

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