

SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

PART I What is the material and what do I need to know in an emergency?**1. PRODUCT IDENTIFICATION****IDENTIFICATION of the SUBSTANCE or PREPARATION:**

TRADE NAME: ProAir[®] HFA Aerosol, Metered (and with dose counter)
CHEMICAL NAME: For Active Ingredient: Albuterol Sulfate: α_1 [(tert-butylamino) methyl]-4-hydroxy-m-xylene- α , α' -diol sulfate (2:1) (salt)
CHEMICAL CLASS: Active Ingredient: Phenethylamine
THERAPEUTIC CLASS: Beta₂-Adrenergic Bronchodilator
RELEVANT USE of the PRODUCT: Human Pharmaceutical

COMPANY/UNDERTAKING IDENTIFICATION:

U.S. SUPPLIER/MANUFACTURER'S NAME: TEVA
ADDRESS: 1090 Horsham Road
 North Wales, PA 19454
 215-591-3000 [08:00 AM --> 05:00 PM]
BUSINESS PHONE:
EUROPEAN SUPPLIER/MANUFACTURER'S NAME: TEVA/TAPI
ADDRESS: Sicor sri-Via Terrazzano
 77-20017 Cho (MI), Italy
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EMERGENCY PHONE: United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtec) [24-hrs]
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DATE OF PREPARATION: July 14, 2012
DATE OF REVISION: New

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2004 format. This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The product is also classified per all applicable EU Directives through EC 1907/2006, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are exempted from classification and other criteria of 1272/2008.

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW: Product Description: This product consists of a white, crystalline powder solubilized in ethanol, and delivered in a pressurized container by a non-flammable gas. **Health Hazards:** Inhalation of high quantity may be harmful. Skin and eye contact may cause irritation. Prolonged skin contact may cause defatting of the skin. Ingestion is not a likely route of exposure. The most common adverse effects from therapeutic use of this product have been headache, tachycardia, pain, dizziness, pharyngitis, and rhinitis. Deliberate 'sniffing' of this product can be harmful, causing headache, nausea, dizziness and weakness and other adverse central nervous system effects and adverse effects on the heart. In therapeutic use, the most common adverse effect has been nasal irritation, prolonged sneezing and burning sensation in the nose. Severe allergic reaction, including anaphylaxis has been reported. The active ingredient is a suspect reproductive toxin. See Section 11 (Toxicological Information) for more information on possible therapeutic use effects. If a release of many containers of this product occurs at the same time, an oxygen-deficient environment can occur, resulting in a hazard of asphyxiation. If containers are heated or punctured, rupture may occur, and may cause injury. **Flammability Hazards:** This product is not normally flammable. May burn if highly heated or if subjected to direct flame. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (carbon, nitrogen and sulfur oxides, hydrogen fluoride, carbonyl fluoride, vinylidene fluoride, hydrogen chloride, and carbon oxides). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** Because of the potential global warming and ozone depletion effects caused by the 1,1,1,2-Tetrafluoroethane component, this product should be released to the environment only as a last resort. **Emergency Recommendations:** Emergency responders must wear personal protective equipment suitable for the situation to which they are responding. Persons responding to an emergency such as a fire that involves this product must take precautions to avoid potential injury from containers that rupture.

~Verified on 2012-11 by Henry Schein to be the most current version of the MSDS. To be verified again on 2015-11. ~

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/v	EU Classification (67/548/EEC) GHS and EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
ACTIVE INGREDIENT				
Albuterol Sulfate 5-Methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, magnesium salt (2:1)]	51022-70-9	256-916-8	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Reproductive Toxicity Cat. 2, Harmful Risk Phrase Codes: R63, R20/22, R42, R68/20 Hazard Symbols: Xn GHS and EU 1272/2008 Classification: Reproductive Cat. 2, Acute Oral Toxicity Cat. 4, Acute Inhalation Toxicity Cat. 5, Respiratory Sensitization Cat. 1, STOT (Inhalation-Cardiovascular System) SE Cat. 2 Hazard Codes: H361d, H302, H333, H334, H371 Hazard Symbol/Pictogram: GHS07, GHS08
EXCIPIENTS				
Ethanol, Dehydrated	64-17-5	200-578-6	Proprietary	EU 67/548 Classification: Highly Flammable Risk Phrase Codes: R11 Hazard Symbols: F GHS and EU 1272/2008 Classification: Flammable Liquid Cat. 2 Hazard Codes: H225 Hazard Symbol/Pictogram: GHS02
1,1,1,2-Tetrafluoroethane	811-97-2	212-327-0	Balance	SELF-CLASSIFICATION EU 67/548 Classification: Not Applicable Risk Phrase Codes: Not Applicable Hazard Symbols: Not Applicable GHS and EU 1272/2008 Classification: Gases under Pressure/Compressed Gas Hazard Codes: H2280 Hazard Symbol/Pictogram: GHS04

See Section 16 for full classification information of product and components.

PART II What should I do if a hazardous situation occurs?

4. FIRST-AID MEASURES

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Take a copy of this SDS to health professional with victim.

SKIN EXPOSURE: If this product contaminates the skin, begin decontamination with running water. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effects occur after flushing.

EYE EXPOSURE: If this product enters the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect continues after flushing.

INHALATION: If this product inhaled and adverse effect occurs, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects continue after removal to fresh air.

INGESTION: Ingestion is not a likely route of exposure.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing cardiovascular insufficiency, asthma, diabetes mellitus and preexisting asthma may be aggravated by exposure to this product.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Victims of fluorocarbon gas inhalation require management for hypoxic, central nervous system effects, and cardiac symptoms. Patients must be removed from the exposure environment, and high-flow supplemental oxygen should be utilized. The respiratory system should be evaluated for injury, aspiration, or pulmonary edema and treated appropriately. Central nervous system findings should be treated supportively. A calm environment with no physical exertion is imperative to avoid increasing endogenous adrenergic levels. Exogenous adrenergic drugs must not be used to avoid inducing sensitized myocardial dysrhythmias. Atropine is ineffective in treating bradyarrhythmias. For ventricular dysrhythmias, diphenylhydantoin and counter-shock may be effective.

As with all sympathomimetic aerosol medications, cardiac arrest and even death may be associated with abuse of Albuterol Sulfate. Treatment consists of discontinuation of Albuterol Sulfate together with appropriate symptomatic therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of Albuterol Sulfate. If the patient needs more doses of Albuterol Sulfate than usual, this may be a marker of destabilization of asthma and requires reevaluation of the patient and the treatment regimen, giving special consideration of the possible need for anti-inflammatory treatment (e.g., corticosteroids).

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not flammable.

AUTOIGNITION TEMPERATURE: Not available for product.

For Ethanol: 363°C (685°F); For 1,1,1,2-Tetrafluoroethane: > 743°C (>1369°F)

FLAMMABLE LIMITS (in air by volume, %): Not available for product.

5. FIRE-FIGHTING MEASURES (Continued)

FIRE EXTINGUISHING MEDIA: Unless incompatibilities exist for surrounding materials, water spray, 'ABC' type chemical extinguishers, carbon dioxide, foam, dry chemical and halon extinguishers can be used to fight fires involving this product.

UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

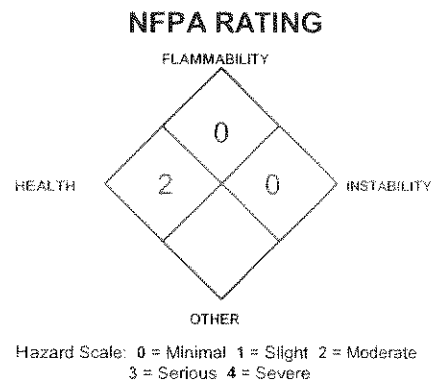
SPECIAL HAZARDS ARISING FROM THE SUBSTANCE: The solution can burn if heated above > 743°C (>1369°F) or if subjected to direct flame for a prolonged period. Containers of this product may rupture in heat of fire. During a fire, irritating/toxic hydrogen fluoride, carbonyl fluoride, vinylidene fluoride, hydrogen chloride, and carbon, nitrogen and sulfur oxides may be generated. If large quantity of product containers rupture, the gas can accumulate in confined spaces and low areas, resulting in an oxygen deficiency hazard.

Explosion Sensitivity to Mechanical Impact: Not applicable.

Explosion Sensitivity to Static Discharge: May be sensitive.

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Structural fire-fighters

must wear Self-Contained Breathing Apparatus and full protective equipment. Chemical resistant clothing may be necessary. Responders must protect all downwind exposures from inhalation of aerosols and decomposition products. Move containers from fire area if it can be done without risk to personnel. Water fog or spray can also be used by trained fire-fighters to disperse mists from this product and to protect personnel. Rinse contaminated equipment thoroughly with sodium thiosulfate solution before returning such equipment to service. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.



6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Release of a single product container presents minimal hazards. In the event release of a large quantity of containers, clear the area and protect people. Trained personnel using pre-planned procedures should respond to uncontrolled releases. Eliminate all sources of ignition before cleanup begins. Use non-sparking tools. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA). Monitor area and confirm levels are below exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area.

PROTECTIVE EQUIPMENT:

Small Release/Release in Hoods: If residual solution is present after release of a single container, personnel wearing gowns, double surgical latex gloves and eye protection should immediately clean spills of less than 5 mL and outside a hood.

Large Release: Use proper protective equipment, including double latex or nitrile gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. If release occurs in confined space or low-lying area, resulting in possible oxygen-deficient atmosphere, wear Self-Contained Breathing Apparatus (SCBA) until area is adequately vented and oxygen level is confirmed to be in breathable range.

METHODS FOR CLEAN-UP AND CONTAINMENT:

Cleanup of Small Release: Residual liquids should be wiped with absorbent gauze pads or similar material. Clean the spill area (three times) using a bleach and detergent solution and then rinse with clean water.

Release in Hoods: Decontamination of all interior hood surfaces may be required after the above procedures have been followed. If the HEPA filter of a hood is contaminated label the unit "Do not use-contaminated" and have trained personnel wearing appropriate protective equipment change and dispose of the filter properly as soon as possible.

Large Release: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. Restrict access to the release area. Ensure area is well-ventilated to avoid oxygen-deficiency and accumulation of combustible vapors. For residual liquid spills of amounts larger than 5 mL limit spread by gently covering with absorbent sheets or spill-control pads or pillows. Any absorbent material used should not react with Ethanol. Be sure not to generate aerosols. The dispersion of mists or sprays into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.

All Spills: Place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, Provincial and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). See information for additional spill response procedures under 'Environmental Precautions' in this Section.

ENVIRONMENTAL PRECAUTIONS: Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer.

REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. See Section 13, Disposal Considerations for more information.

PART III *How can I prevent hazardous situations from occurring?*

7. HANDLING and STORAGE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Avoid generation of aerosols.

7. HANDLING and STORAGE (Continued)

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store this product in original container at controlled room temperature of 20-25°C (68-77°F). Inspect containers of this product for leaks or damage. Store away from incompatible materials (see Section 10, Stability and Reactivity).

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

VENTILATION AND ENGINEERING CONTROLS: Not necessary under normal conditions of handling. Provide adequate ventilation to control possible exposure to components.

WORKPLACE EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							OTHER mg/m ³
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH IDLH ppm	
		TWA ppm	STEL ppm	TWA ppm	STEL ppm	TWA ppm	STEL ppm		
Albuterol Sulfate	51022-70-9	NE	NE	NE	NE	NE	NE	NE	NE
Ethanol	64-17-5	NE	1000	1000	NE	1000	NE	3300 (based on 10% of LEL)	DFG MAKs: TWA = 500 PEAK = 2•MAK 15 min average value, 1-hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C DFG MAK Mutagen Category: 5 Carcinogen: MAK-5, TLV-A3
1,1,1,2-Tetrafluoroethane	811-97-2	NE	NE	NE	NE	NE	NE	NE	DFG MAKs: TWA = 1000 PEAK = 8•MAK 15 min average value, 1-hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C AIHA WEELS: TWA = 1000

NE = Not Established

See Section 16 for Definitions of Other Terms Used

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: Currently, there are no limits in place for the active ingredient of this product. The following limits are available for the excipients. Limits change or are added and should be checked for currency.

ETHANOL:

Australia: TWA = 1000 ppm (1880 mg/m³), JUL 2008
 Belgium: TWA = 1000 ppm (1907 mg/m³), MAR 2002
 Denmark: TWA = 1000 ppm (1900 mg/m³), OCT 2002
 Finland: TWA = 1000 ppm (1900 mg/m³), STEL = 1300 ppm (2500 mg/m³), SEP 2009
 France: VME = 1000 ppm (1900 mg/m³), VLE = 5000 ppm (9500), FE B2006
 Germany: MAK = 960 mg/m³ (500 mL/m³), 2005
 Hungary: TWA = 1900 mg/m³, STEL = 7600 mg/m³, SEP 2000
 Korea: TWA = 1000 ppm (1900 mg/m³), 2006
 Mexico: TWA = 1000 ppm (1900 mg/m³), 2004
 The Netherlands: MAC-TGG = 1000 mg/m³, 2003
 New Zealand: TWA = 1000 ppm (1880 mg/m³), JAN 2002
 Norway: TWA = 500 ppm (950 mg/m³), JAN 1999
 The Philippines: TWA = 1000 ppm (1900 mg/m³), JAN 1993
 Poland: MAC(TWA) = 1000 mg/m³, MAC(STEL) = 3000 mg/m³, JAN 1999
 Russia: TWA = 1000 mg/m³, STEL = 2000 mg/m³, JUN 2003

ETHANOL (continued):

Sweden: TWA = 500 ppm (1000 mg/m³); STEL = 1000 ppm (1900 mg/m³), JUN 2005
 Switzerland: MAK-W = 500 ppm (960 mg/m³), KZG-W = 1000 ppm (1920 mg/m³), DEC 2006
 Thailand: TWA = 1000 ppm (1900 mg/m³), JAN 1993
 Turkey: TWA = 1000 ppm (1900 mg/m³), JAN 1993
 United Kingdom: TWA = 1000 ppm (1920 mg/m³), 2005
 In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV
1,1,1,2-TETRAFLUOROETHANE:
 Australia: TWA = 1000 ppm (4240 mg/m³), JUL 2008
 Germany: MAK = 4200 mg/m³ (1000 mL/m³), 2005
 The Netherlands: MAC-TGG = 4200 mg/m³, 2003
 New Zealand: TWA = 1000 ppm, JAN 2002
 Russia: STEL = 3000 mg/m³, JUN 2003
 Sweden: TWA = 500 ppm (2000 mg/m³); STEL = 750 ppm (3000 mg/m³), JUN 2005
 Switzerland: MAK-W = 1000 ppm (4200 mg/m³), DEC 2006
 United Kingdom: TWA = 1000 ppm (4240 mg/m³), 2005

PROTECTIVE EQUIPMENT: The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR 1910.132), equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02, Z94.3-M1982, Industrial Eye and Face Protectors and CSA Standard Z195-02, Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: Not needed under normal circumstances of use. Maintain airborne contaminant concentrations below exposure limits listed above if applicable. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998). The following are NIOSH respiratory protective equipment for Ethanol and are provided to assist in selection of respiratory equipment should mists or sprays be present and respiratory equipment is necessary.

ETHANOL

CONCENTRATION RESPIRATORY PROTECTION

Up to 3300 ppm: Any Supplied-Air Respirator (SAR), or any Self-Contained Breathing Apparatus (SCBA) with a full facepiece.
 Emergency or Planned Entry into Unknown Concentrations or IDLH Conditions: Any SCBA that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode, or any SAR that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary SCBA operated in pressure-demand or other positive-pressure mode.

Escape: Any appropriate escape-type, SCBA.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

PROTECTIVE EQUIPMENT (continued):

EYE PROTECTION: No eye protection is normally needed during medical administration of this product. During operations in which mists or sprays of the product may be generated, splash goggles or safety glasses should be considered. If necessary, refer to appropriate regulations.

HAND PROTECTION: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. If necessary refer to appropriate regulations.

SKIN PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.

9. PHYSICAL and CHEMICAL PROPERTIES

PHYSICAL FORM: Aerosol gas.

COLOR: Clear.

MOLECULAR WEIGHT: For Active Ingredient: 576.7

MOLECULAR FORMULA: For Active Ingredient: $(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$

ODOR: Ethereal

pH: Not available.

ODOR THRESHOLD: For Ethanol: Geometric mean: 180 ppm (detection); 100 ppm (recognition).

VAPOR PRESSURE @ 25°C: 96 psia

VAPOR DENSITY @ 25°C (air = 1): 3.6

OXIDIZING PROPERTIES: Not an oxidizer.

FLAMMABILITY: Not flammable.

FREEZING POINT: Not available.

BOILING POINT:

FLASH POINT: Not applicable.

AUTOIGNITION TEMPERATURE: Not applicable.

DECOMPOSITION TEMPERATURE: Not available.

SPECIFIC GRAVITY: 1.2 g/ml

EXPLOSIVE PROPERTIES: Not explosive.

EVAPORATION RATE (n-butyl acetate = 1): For Ethanol: 2.4

SOLUBILITY IN WATER: 15 % weight

OTHER SOLUBILITIES: For active: Slightly soluble in ethanol.

PERCENT VOLATILE: >=99 %

VOC LESS H₂O and EXEMPT SOLVENTS: Not available.

COEFFICIENT OF OIL/WATER DISTRIBUTION (PARTITION COEFFICIENT): For Active Ingredient: Log Kow: 0.64; Log P: 0.02 (predicted); For Ethanol: Log P(oct) = -0.31 (experimental)

HOW TO DETECT THIS SUBSTANCE (identification/warning properties): There are no good characteristics of this product to identify it in event of accidental release.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Normally stable.

DECOMPOSITION PRODUCTS: *Combustion:* Products of thermal decomposition may include hydrogen fluoride, carbonyl fluoride, vinylidene fluoride, hydrogen chloride, and carbon, nitrogen and sulfur oxides. *Hydrolysis:* None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Incompatible with alkaline and alkaline earth materials.

POSSIBILITY OF HAZARDOUS REACTION/POLYMERIZATION: Not expected to occur.

CONDITIONS TO AVOID: Exposure to or contact with extreme temperatures, combustible materials, incompatible chemicals.

PART IV *Is there any other useful information about this material?*

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The main route of occupational exposure to this product is via inhalation of mists or sprays and skin contact. The anticipated symptoms of exposure, by route of exposure are described further in this section.

INHALATION: Inhalation may cause respiratory irritation. Non-therapeutic inhalation may be harmful. Inhalation may cause sensitization of the heart to adrenaline, which may result in abnormal rapid heart rate (tachycardia), irregular heart beat (cardiac arrhythmias) and depression of cardiac function. Inhalation may also cause adverse effects, as described under 'Other Health Effects'.

CONTACT WITH SKIN or EYES: Contact with the eyes may cause immediate irritation. Skin contact may be irritating, especially if prolonged. Chronic skin exposure may cause defatting of the skin.

SKIN ABSORPTION: No data are available on potential absorption of this product.

INGESTION: Ingestion is not a likely route of occupational exposure to this product.

INJECTION: Not a likely route of exposure.

OTHER HEALTH HAZARDS: In event that rupture occurs of a large quantity of containers, especially in a confined space, an oxygen-deficient environment may be created due to the release of the propellant gas. Individuals breathing such an atmosphere may experience symptoms which include headaches, ringing in ears, dizziness, drowsiness, unconsciousness, nausea, vomiting, and depression of all the senses. Under some circumstances of exposure, death may occur. The effects associated with various levels of oxygen are as follows:

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, this product can cause the following adverse effect symptoms by body system:

- **Cardiovascular:** Tachycardia
- **Musculoskeletal:** Pain
- **Nervous System:** Dizziness
- **Respiratory System:** Pharyngitis, rhinitis

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses (continued):

The expected symptoms to Albuterol Sulfate with overdosage are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of symptoms such as seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats per minute, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, insomnia, and exaggeration of the pharmacological effects given in this section. Hypokalemia may also occur.

The oral median lethal dose of Albuterol Sulfate in mice is greater than 2000 mg/kg (approximately 580 times the maximum recommended daily inhalation dose of Albuterol Sulfate on a mg/m² basis). The subcutaneous median lethal dose of Albuterol Sulfate in mature rats and small young rats is approximately 450 mg/kg and 2000 mg/kg, respectively (approximately 260 and 1200 times the maximum recommended daily inhalation dose of Albuterol Sulfate on a mg/m² basis). The inhalation median lethal dose has not been determined in animals. Other effects described by body systems may include:

- **Cardiovascular:** Pulse rate, blood pressure. Beta-agonists have been reported to produce ECG changes, such as flattening of the T-wave, prolongation of the QTc interval, and ST segment depression.
- **Respiratory System:** As with other inhaled beta-adrenergic agonists, Albuterol Sulfate can produce paradoxical bronchospasm, which may be life threatening.
- **Other:** Large doses of intravenous Albuterol have been reported to aggravate pre-existing diabetes mellitus and ketoacidosis. As with other beta-agonists, inhaled and intravenous Albuterol may produce a significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects.

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: Non-therapeutic inhalation may be harmful. May cause irritation to respiratory system, skin and eyes.

Chronic: Defatting of the skin may occur after chronic, low-level skin contact. Inhalation may cause cardiac sensitization or severe allergic reaction in susceptible individuals. Contains suspect reproductive toxin. Other health effects may occur as described under 'Other Health Effects-Therapeutic Use' may also occur.

TARGET ORGANS: **Acute:** Occupational Exposure and Therapeutic Use: Skin, eyes, respiratory system. **Chronic:** Occupational Exposure: Skin. Therapeutic Use: See information under 'Other Health Effects'.

TOXICITY DATA: The following toxicity data are currently available for components. Only available Human data, LD50 Oral-Rat and Mouse, LD50 Skin-Rabbit, LC50 Inhalation-Rat and Mouse and Irritancy Test data are presented in this SDS, due to the volume of data available. For information on additional data available, contact Teva for more information.

ALBUTEROL SULFATE:

LD₅₀ (Oral-Rat) > 2500 mg/kg
LD₅₀ (Oral-Mouse) 1950 mg/kg

ETHANOL:

Open Irritation Test (Skin-Rabbit) 400 mg; Mild
Standard Draize Test (Skin-Rabbit) 20 mg/24 hours: Moderate

Standard Draize Test (Eye-Rabbit) 500 mg; Severe
Standard Draize Test (Eye-Rabbit) 500 mg/24 hours: Mild
Rinsed with Water (Eye-Rabbit) 100 mg/ seconds: Moderate

TDLo (Oral-Human) 22,500 mg/kg/4 weeks-intermittent: Endocrine: other changes; Blood: other changes

TDLo (Oral-Human) 0.5 mg/kg; Behavioral: changes in psychophysiological tests

TDLo (Oral-Human) 400 mg/kg; Behavioral: alteration of operant conditioning

TDLo (Oral-Human) 0.5 gm/kg; Behavioral: somnolence (general depressed activity), changes in psychophysiological tests

TDLo (Oral-Human) 1.4 gm/kg; Behavioral: euphoria, changes in psychophysiological tests; Gastrointestinal: nausea or vomiting

TDLo (Oral-Infant) 11,712 µL/kg; Behavioral: general anesthetic; Cardiac: arrhythmias (including changes in conduction); Lungs, Thorax, or Respiration: dyspnea

TDLo (Oral-Human) 0.7 gm/kg/10 minutes: Behavioral: changes in psychophysiological tests

TDLo (Oral-Child) 14400 mg/kg/30 minutes (intermittent): Behavioral: coma; Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting

TDLo (Oral-Woman) 1200 mg/kg/3 hours: Endocrine: changes in gonadotropins; Endocrine: other changes; Blood: other changes

ETHANOL (continued):

TDLo (Oral-Woman) 256 gm/kg/12 weeks: Behavioral: hallucinations, distorted perceptions; Endocrine: effect on menstrual cycle

TDLo (Oral-Woman) 0.7 gm/kg; Behavioral: changes in psychophysiological tests

TDLo (Oral-Woman) 41 gm/kg; female 41 week(s) after conception: Reproductive: Effects on Newborn: Apgar score (human only), other neonatal measures or effects, drug dependence

TDLo (Oral-Woman) 250 mg/kg; female 37 week(s) after conception: Reproductive: Effects on Embryo or Fetus: other effects to embryo

TDLo (Oral-Woman) 5860 mL/kg; female 3 year(s) pre-mating: 100 day(s) post-birth: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue); Effects on Newborn: behavioral, delayed effects

TDLo (Oral-Man) 3371 µL/kg; Behavioral: altered sleep time (including change in righting reflex), excitement, coma

TDLo (Oral-Man) 700 mg/kg; Behavioral: changes in psychophysiological tests

TDLo (Oral-Man) 50 mg/kg; Gastrointestinal: alteration in gastric secretion, other changes

TDLo (Oral-Man) 1430 µg/kg; Behavioral: changes in motor activity (specific assay), ataxia, antipsychotic

TDLo (Intravenous-Human) 0.89 mL/kg; Vascular: regional or general arteriolar constriction, measurement of regional blood flow

TDLo (Intravenous-Human) 1.6 gm/kg/6 hours: Biochemical: Metabolism (intermediary): other

TDLo (Intravenous-Man) 0.57 gm/kg; Behavioral: changes in psychophysiological tests



HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
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FLAMMABILITY HAZARD	(RED)	0
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PHYSICAL HAZARD	(YELLOW)	0
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PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	See Section 8		See Section 8

For Routine Industrial Use and Handling Applications

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate
3 = Serious 4 = Severe * = Chronic hazard

11. TOXICOLOGICAL INFORMATION (Continued)

CARCINOGENIC POTENTIAL OF COMPONENTS: In a 2-year study in Sprague-Dawley rats, Albuterol Sulfate caused a significant dose-related increase in the incidence of benign leiomyomas of the mesovarium and above dietary doses of 2 mg/kg (approximately equivalent to the maximum recommended daily inhalation dose for Albuterol Sulfate on a mg/m² basis). In another study, this effect was blocked by the co-administration of propranolol, a non-selective beta-adrenergic antagonist. In an 18-month study in CD-1 mice, Albuterol Sulfate showed no evidence of tumorigenicity at dietary doses up to 500 mg/kg (approximately 140 times the maximum recommended daily inhalation dose of Albuterol Sulfate on a mg/m² basis). In a 22-month study in Golden hamsters, Albuterol Sulfate showed no evidence of tumorigenicity at dietary doses up to 50 mg/kg (approximately 20 times the maximum recommended daily inhalation dose of Albuterol Sulfate on a mg/m² basis).

The Ethanol component is listed by agencies tracking the carcinogenic potential of chemical compounds as follows:

ETHANOL: ACGIH TLV-A3 (Confirmed Animal Carcinogen); MAK-5 (Substances with Carcinogenic and Genotoxic Effects, the potency of which is considered to be so low that, provided the MAK and BAT values are observed, no significant contribution to human cancer risk is to be expected.)

The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be a cancer-causing agent by these agencies.

IRRITANCY OF PRODUCT: This product may be irritating by all routes of exposure.

SENSITIZATION TO THE PRODUCT: The 1,1,1,2-Tetrafluoroethane component can sensitize the heart to epinephrine, based on animal information. Immediate hypersensitivity reactions may occur after administration of Albuterol as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, and oropharyngeal edema.

REPRODUCTIVE TOXICITY INFORMATION: This product is rated as Pregnancy Category C (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks). There are no adequate and well-controlled studies in pregnant women. The following information is available for the product and its components.

Mutagenicity: Albuterol Sulfate was not mutagenic in the Ames test or a mutation test in yeast. Albuterol Sulfate was not clastogenic in a human peripheral lymphocyte assay or in an AH₁ strain mouse micronucleus assay. The 1,1,1,2-Tetrafluoroethane component was not active in the Ames, cytogenetics and in vivo micronucleus assays. 1,1,1,2-Tetrafluoroethane did induce unscheduled DNA synthesis. The Ethanol component is mutagenic, based on positive results (dominant lethality, aneuploidy, sister chromatid exchanges) obtained in the germ cells and somatic cells of tests using live animals. These effects have been observed at very high doses. The mutagenicity of Ethanol has been extensively studied and reviewed. Positive and negative results have been obtained in cultured mammalian cells and bacteria.

Embryotoxicity/Teratogenicity: Various congenital anomalies, including cleft palate and limb defects, have been reported in the offspring of patients being treated with Albuterol. Some of the mothers were taking multiple medications during their pregnancies. Because no consistent pattern of defects can be discerned, a relationship between Albuterol use and congenital anomalies has not been established. Albuterol has been shown to be teratogenic in mice. A study in CD-1 mice given Albuterol subcutaneously showed cleft palate formation in 5 of 111 (4.5%) fetuses at 0.25 mg/kg (less than the maximum recommended daily inhalation dose of Albuterol Sulfate on a mg/m² basis) and cleft palate formation in 10 of 108 (9.3%) fetuses at 2.5 mg/kg (approximately equal to the maximum recommended daily inhalation dose of Albuterol Sulfate on a mg/m² basis). The drug did not induce cleft palate formation when administered subcutaneously at a dose of 0.025 mg/kg (less than the maximum recommended daily inhalation dose of Albuterol Sulfate on a mg/m² basis). Cleft palate formation also occurred in 23 of 72 (30.5%) fetuses from females treated subcutaneously with 2.5 mg/kg isoproterenol (positive control). A reproduction study in Stride rabbits revealed cranioschisis in 7 of 19 (37%) fetuses when Albuterol Sulfate was administered orally at 50 mg/kg (approximately 60 times the maximum recommended daily inhalation dose of Albuterol Sulfate on a mg/m² basis). A study in which pregnant rats were dosed with radio-labelled Albuterol Sulfate demonstrated that drug-related material was transferred from the maternal circulation to the fetus.

Teratogenicity (continued): The harmful effects of the Ethanol component in pregnant animals are well documented. Effects have included fetotoxicity (e.g. delayed growth), embryotoxicity (e.g. increased prenatal mortality), and teratogenicity (e.g. malformations of the central nervous system, facial structures, heart, limbs and urogenital system). As these effects are primarily by ingestion, developmental effects from Ethanol in this product are not likely. The 1,1,1,2-Tetrafluoroethane component did not cause developmental effects in teratology studies with rabbits using exposure levels up to 40,000 ppm.

Reproductive Toxicity: Reproduction studies in rats demonstrated no evidence of impaired fertility at oral doses of Albuterol Sulfate up to 50 mg/kg (approximately 30 times the maximum recommended daily inhalation dose of Albuterol Sulfate on a mg/m² basis).

BIOLOGICAL EXPOSURE INDICES: Currently, there are no Biological Exposure Indices (BEIs) determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for mobility. The following information is available for some components of this product.

ETHYL ALCOHOL:

Using a structure estimation method based on molecular connectivity indices, the Koc can be estimated to be 1. According to a classification scheme, this estimated Koc value suggests that this compound is expected to have very high mobility in soil.

1,1,1,2-TETRAFLUOROETHANE:

Estimated soil adsorption coefficients ranging from 117 to 432 can be calculated for Tetrafluoroethane based on its estimated log octanol/water partition coefficient, 1.274, and estimated water solubility, 67 mg/L at 25°C, in turn estimated from its estimated Henry's Law constant and estimated vapor pressure, using appropriate regression equations. These values indicate that Tetrafluoroethane will display moderate to high mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence and biodegradability. The following information is available for the components of this product.

ETHYL ALCOHOL:

If released to the atmosphere, an extrapolated vapor pressure of 59.3 mm Hg at 25°C indicates that this compound will exist solely in the vapor phase. Vapor phase material is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 5 days. If released to soil, this compound is expected to have very high mobility based upon an estimated Koc of 1. Volatilization from moist soil surfaces is expected to be an important fate process based upon a Henry's Law constant of 5X10⁻⁶ atm-cu m/mole.

12. ECOLOGICAL INFORMATION (Continued)

PERSISTENCE AND BIODEGRADABILITY (continued):

ETHYL ALCOHOL (continued):

This material may also volatilize from dry soils based upon its vapor pressure. Biodegradation is expected to occur rapidly in the environment based on numerous screening tests using different types of inocula and incubation periods. This compound was degraded with half-lives on the order of a few days using microcosms constructed with a low organic sandy soil and groundwater, indicating it is unlikely to be persistent in the environment. If released into water, this material is not expected to adsorb to suspended solids and sediment based upon the estimated *K_{oc}*. Volatilization from water surfaces is expected to be an important fate process based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 3 and 39 days, respectively. Hydrolysis and photolysis in sunlit surface waters are not expected since this compound lacks functional groups that are susceptible to hydrolysis or photolysis under environmental conditions.

1,1,1,2-TETRAFLUOROETHANE:

If released to soil, this compound will rapidly volatilize from either moist or dry soil to the atmosphere. It will display moderate to high mobility in soil. If released to water, this compound will rapidly volatilize to the atmosphere. The estimated half-life for volatilization from a model river is 3.0 hours. If released to the atmosphere, this material will undergo a very slow gas-phase reaction with photochemically produced hydroxyl radicals with an estimated half-life of 187 days. The atmospheric lifetime of Tetrafluoroethane has been estimated to range from 12.5 to 24 years. This material may also undergo atmospheric removal by wet deposition processes; however, any removed is expected to rapidly re-volatilize to the atmosphere.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential. The following information is available for some component of this product.

ETHYL ALCOHOL:

Bioconcentration: An estimated BCF of 3 was calculated, using a log *K_{ow}* of -0.31 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.

1,1,1,2-TETRAFLUOROETHANE:

Estimated bioconcentration factors ranging from 5 to 58 can be calculated for this compound based on its estimated log octanol/water partition coefficient, 1.274, and estimated water solubility, 67 mg/L at 25°C, in turn estimated from its estimated Henry's Law constant and estimated vapor pressure, using appropriate regression equations. These values indicate that this material will not bioconcentrate in fish and aquatic organisms.

ECOTOXICITY: This compound can cause acute and chronic toxicity effects on aquatic organisms. The following aquatic toxicity data are available for the Ethanol component. Only select data are provided in this SDS. Contact Teva for additional information.

ETHANOL:

EC₅₀ (*Chlorella pyrenoidosa* Green algae; growth inhibition) 48 hours = 9310 mg/L; static

EC₅₀ (*Pimephales promelas* fathead minnows) 96 hours = 12.9 g/L

LC₅₀ (*Salmo gairdnerii* Rainbow trout) 96 hours = 13,000 mg/L at 12°C (95% Confidence limit 12000-16000 mg/L), wt 0.8 g /Static bioassay

LC₅₀ (*Pimephales promelas* fathead minnows) 96 hours = 14.2 g/L

ETHANOL (continued):

LC₅₀ (*Poecilia reticulata* Guppy) 24 hours = 12,500 mg/L

LC₅₀ (*Leuciscus idus melanotus* Golden orfe) 48 hours = 8140 mg/L; static

LC₅₀ (*Danio rerio* Zebrafish) 24 hours = >100 mg/L; static

LC₅₀ (*Daphnia magna* Water flea) 48 hours = 11,853-13248 mg/L; static, 20°C

LC₅₀ (*Oryzias latipes* Medaka) 24 hours = 5106 mg/L; static

LC₅₀ (*Oryzias latipes* Medaka) 48 hours = 1350 mg/L; static

OTHER ADVERSE EFFECTS: The 1,1,1,2-Tetrafluoroethane component has been atmospherically modeled for its impact on depleting ozone and as a contributor to global warming. Research suggests that over the past 10 years the concentration of Tetrafluoroethane has increased significantly in the Earth atmosphere, with a recent study revealing a doubling in atmospheric concentration between 2001-2004. It has insignificant ozone depletion potential (ozone layer), significant global warming potential (GWP₁₀₀ = 1300) and negligible acidification potential (acid rain). Tetrafluoroethane is slowly converted to trifluoroacetic acid through a radical reaction in the upper atmosphere and leads to a detectable amount of several ng/L in acid rain.

RESULTS OF PBT AND vPvB ASSESSMENT: No data available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Incineration is recommended. Reusable equipment should be cleaned with soap and water. It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters.

DISPOSAL CONTAINERS: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

U.S. EPA WASTE NUMBER: Not applicable.

EWG WASTE CODE: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is exempt from classification as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101. Exceptions for small quantity aerosols apply. Refer to 49 CFR 173.306(J), 'Aerosols and Small Receptacles'.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product does not meet the criteria as Dangerous Goods, per regulations of Transport Canada. In order to meet exemption for aerosols, all requirements under TDG and container requirements per Canadian General Standards Board (CGSB), CGSB- 43.123-2010: Aerosol Containers and Gas Cartridges for Transport of Dangerous Goods, must be met.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is exempt from classification as Dangerous Goods, per rules of IATA. Exceptions per Special Provision A98 apply to small quantity aerosols.

14. TRANSPORTATION INFORMATION (Continued)

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is excepted from classification as Dangerous Goods by the International Maritime Organization, under limited quantity exemption. Exemption is predicate on requirements of SP277 being met.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is exempt from shipping as Dangerous Goods of the United Nations Economic Commission for Europe. Provisions for aerosols must be met, per ADR Volume II, Part 3, Chapter 3.3.1 (190).

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN); no component is specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. SARA HAZARD CATEGORIES (SECTION 311/312, 40 CFR 370-21): ACUTE: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: Yes

U.S. CERCLA REPORTABLE QUANTITY (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards; this product is not subject to requirements under TSCA

OTHER U.S. FEDERAL REGULATIONS: Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No component is listed on the California Proposition 65 Lists.

ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL/NDL STATUS: This product is regulated by the Therapeutic Products Programme (TPP) of Health Canada; it is exempt from the requirements of CEPA.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITY SUBSTANCES LISTS: The 1,1,1,2-Tetrafluoroethane component has CEPA Reporting Requirements as a Greenhouse gas subject to mandatory reporting by June 1, 2008

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

ADDITIONAL EUROPEAN REGULATIONS:

SAFETY, HEALTH, AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE PRODUCT: Formulated, finished medicinal products for human use, are subject to Directive 2001/83/EC and subsequent amendments to the directive. In addition, related to aerosols, this product may have requirements under Annex to Council Directive 75/324/EEC⁴, as amended and applicable at the date of manufacture of this product.

CHEMICAL SAFETY ASSESSMENT: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

ANSI LABELING (Z129.1, Provided to Summarize Occupational Hazard Information): **WARNING!** MAY BE HARMFUL IF LARGE QUANTITY IS INHALED. CAN CAUSE SERIOUS ALLERGIC REACTION IN SUSCEPTIBLE INDIVIDUALS. CONTAINS SUSPECT REPRODUCTIVE TOXIN. IF RELEASED IN LARGE QUANTITY, REDUCES OXYGEN AVAILABLE FOR BREATHING. CONTENTS UNDER PRESSURE. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 49°C (120°F) may cause bursting. Never throw container into fire or incinerator. Do not get in eyes. Non-therapeutic breathing should be avoided. Use only with adequate ventilation. Wash thoroughly after handling. Wear gloves, goggles, facemasks, suitable body protection, and NIOSH-approved respiratory protection, as appropriate. **FIRST-AID:** in case of contact, immediately flush skin or eyes with plenty of water for at least 20 minutes while removing contaminated clothing and shoes. If inhaled, remove to fresh air. Get medical attention if necessary. **IN CASE OF FIRE:** Move containers from fire area only if this can be done safely. **IN CASE OF RELEASE:** Allow containers to release in area. Ventilate area and confirm oxygen level prior to entry into area. Consult Safety Data Sheet for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

16. OTHER INFORMATION (Continued)

67/548/EEC EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION FOR COMPONENTS:

Full Text Global Harmonization AND EU CLP Regulation (EC) 1272/2008:

Albuterol Sulfate: This is a self classification.

Classification: Reproductive Category 2, Acute Oral Toxicity Category 4, Acute Inhalation Toxicity Category 5, Respiratory Sensitization Category 1, Specific Target Organ Toxicity (Inhalation-Cardiovascular System) Single Exposure Category 2

Hazard Statement Codes: H361d: Suspected of damaging the unborn child. H302: Harmful if swallowed. H333: May be harmful if inhaled. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H371: May cause damage to cardiovascular system by ingestion.

Ethanol: This is a published classification.

Classification: Flammable Liquid Category 2

Hazard Statement Codes: H225: Highly flammable liquid and vapour.

1,1,1,2-Tetrafluoroethane: This is a self classification.

Classification: Gases under Pressure/Compressed Gas

Hazard Statement Codes: H280: Contains gas under pressure; may explode if heated.

Full Text EU 67/548/EEC:

Albuterol Sulfate: This is a self classification.

Classification: Reproductive Toxicity Category 2, Harmful

Risk Phrases: R63: Possible risk of harm to the unborn child. R20/22: Harmful by inhalation and if swallowed. R42: May cause sensitisation by inhalation. R68/20: Harmful; possible risk of irreversible effects through inhalation.

Ethanol: This is a published classification.

Classification: Flammable

Risk Phrases: R11: Highly Flammable

1,1,1,2-Tetrafluoroethane: Simple Asphyxiant Gases are not classified under 67/548/EEC

Classification: Not applicable.

Risk Phrases: Not applicable.

REVISION DETAILS: New

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721-1961 • (800) 441-3365

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REVISION HISTORY: New.

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DEFINITIONS OF TERMS

For information on medical terms used in this SDS consult an on-line database such as Medline Plus; <http://www.nlm.nih.gov/medlineplus/druginformation.html>. A large number of abbreviations and acronyms appear on a SDS. Some of these, which are commonly used, include the following:

CAS #: This is the Chemical Abstract Service Number that uniquely identifies each constituent.

EXPOSURE LIMITS IN AIR:

CEILING LEVEL: The concentration that shall not be exceeded during any part of the working exposure.

ACGIH - American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

DFG MAK Germ Cell Mutagen Categories: 1: Germ cell mutagens which have been shown to increase the mutant frequency in the progeny of exposed humans. 2: Germ cell mutagens which have been shown to increase the mutant frequency in the progeny of exposed mammals.

3A: Substances which have been shown to induce genetic damage in germ cells of human of animals, or which produce mutagenic effects in somatic cells of mammals *in vivo* and have been shown to reach the germ cells in an active form. **3B:** Substances which are suspected of being germ cell mutagens because of their genotoxic effects in mammalian somatic cell *in vivo*; in exceptional cases, substances for which there are no *in vivo* data, but which are clearly mutagenic *in vitro* and structurally related to known *in vivo* mutagens. **4:** Not applicable (Category 4 carcinogenic substances are those with non-genotoxic mechanisms of action. By definition, germ cell mutagens are genotoxic. Therefore, a Category 4 for germ cell mutagens cannot apply. At some time in the future, it is conceivable that a Category 4 could be established for genotoxic substances with primary targets other than DNA [e.g. purely aneugenic substances] if research results make this seem sensible.) **5:** Germ cell mutagens, the potency of which is considered to be so low that, provided the MAK value is observed, their contribution to genetic risk for humans is expected not to be significant.

DFG MAK Pregnancy Risk Group Classification: **Group A:** A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can lead to damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed. **Group B:** Currently available information indicates a risk of damage to the developing embryo or fetus must be considered to be probable. Damage to the developing organism cannot be excluded when pregnant women are exposed, even when MAK and BAT values are observed. **Group C:** There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are observed. **Group D:** Classification in one of the groups A-C is not yet possible because, although the data available may indicate a trend, they are not sufficient for final evaluation.

IDLH-Immediately Dangerous to Life and Health: This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury.

LOQ: Limit of Quantitation.

MAK: Federal Republic of Germany Maximum Concentration Values in the workplace.

NE: Not Established. When no exposure guidelines are established, an entry of NE is made for reference.

NIC: Notice of Intended Change.

EXPOSURE LIMITS IN AIR (continued):

NIOSH CEILING: The exposure that shall not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling shall be assumed as a 15-minute TWA exposure (unless otherwise specified) that shall not be exceeded at any time during a workday.

NIOSH RELs: NIOSH's Recommended Exposure Limits.

PEL-Permissible Exposure Limit: OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL," is placed next to the PEL that was vacated by Court Order.

SKIN: Used when a there is a danger of cutaneous absorption.

STEL-Short Term Exposure Limit: Short Term Exposure Limit, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA.

TLV-Threshold Limit Value: An airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour.

TWA-Time Weighted Average: Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS: This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.

HEALTH HAZARD: 0 (Minimal Hazard): No significant health risk; irritation of skin or eyes not anticipated. *Skin Irritation:* Essentially non-irritating. *PII or Draize = "0".* *Eye Irritation:* Essentially non-irritating, or minimal effects which clear in < 24 hours [e.g. mechanical irritation]. *Draize = "0".* *Oral Toxicity LD₅₀ Rat:* < 5000 mg/kg. *Dermal Toxicity LD₅₀ Rat or Rabbit:* < 2000 mg/kg. *Inhalation Toxicity 4-hrs LC₅₀ Rat:* < 20 mg/L; **1 (Slight Hazard):** Minor reversible injury may occur; slightly or mildly irritating. *Skin Irritation:* Slightly or mildly irritating. *Eye Irritation:* Slightly or mildly irritating. *Oral Toxicity LD₅₀ Rat:* > 500-5000 mg/kg. *Dermal Toxicity LD₅₀ Rat or Rabbit:* > 1000-2000 mg/kg. *Inhalation Toxicity LC₅₀ 4-hrs Rat:* > 2-20 mg/L; **2 (Moderate Hazard):** Temporary or transitory injury may occur. *Skin Irritation:* Moderately irritating; primary irritant; sensitizer. *PII or Draize > 0, < 5.* *Eye Irritation:* Moderately to severely irritating and/or corrosive; reversible corneal opacity; corneal involvement or irritation clearing in 8-21 days. *Draize > 0, < 25.* *Oral Toxicity LD₅₀ Rat:* > 50-500 mg/kg. *Dermal Toxicity LD₅₀ Rat or Rabbit:* > 200-1000 mg/kg. *Inhalation Toxicity LC₅₀ 4-hrs Rat:* > 0.5-2 mg/L; **3 (Serious Hazard):** Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation:* Severely irritating and/or corrosive; may destroy dermal tissue, cause skin burns, dermal necrosis. *PII or Draize > 5-8* with destruction of tissue.

DEFINITIONS OF TERMS (Continued)

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

HEALTH HAZARD (continued): 3 (continued): *Eye Irritation:* Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. Oral Toxicity LD₅₀ Rat: > 1-50 mg/kg. Dermal Toxicity LD₅₀Rat or Rabbit: > 20-200 mg/kg. Inhalation Toxicity LC₅₀ 4-Hrs Rat: > 0.05-0.5 mg/L; 4 (Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposure. *Skin Irritation:* Not appropriate. Do not rate as a "4", based on skin irritation alone. *Eye Irritation:* Not appropriate. Do not rate as a "4", based on eye irritation alone. Oral Toxicity LD₅₀ Rat: ≤ 1 mg/kg. Dermal Toxicity LD₅₀Rat or Rabbit: ≤ 20 mg/kg. Inhalation Toxicity LC₅₀ 4-Hrs Rat: ≤ 0.05 mg/L).

FLAMMABILITY HAZARD: 0 (Minimal Hazard-Materials that will not burn in air when exposure to a temperature of 815.5°C [1500°F] for a period of 5 minutes.); 1 (Slight Hazard-Materials that must be pre-heated before ignition can occur. Material require considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur. Including: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C [200°F] (e.g. OSHA Class IIIB, or; Most ordinary combustible materials [e.g. wood, paper, etc.]; 2 (Moderate Hazard-Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres in air. Including: Liquids having a flash-point at or above 37.8°C [100°F]; Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp; Solids and semisolids that readily give off flammable vapors.); 3 (Serious Hazard- Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions, including: Liquids having a flash point below 22.8°C [73°F] and having a boiling point at or above 38°C [100°F] and below 37.8°C [100°F] [e.g. OSHA Class IB and IC]; Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air [e.g., dusts of combustible solids, mists or droplets of flammable liquids]; Materials that burn extremely rapidly, usually by reason of self-contained oxygen [e.g. dry nitrocellulose and many organic peroxides]; 4 (Severe Hazard-Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and which will burn readily, including: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C [73°F] and a boiling point below 37.8°C [100°F] [e.g. OSHA Class IA; Material that ignite spontaneously when exposed to air at a temperature of 54.4°C (130°F) or below [e.g. pyrophoric].

PHYSICAL HAZARD: 0 (Water Reactivity: Materials that do not react with water. *Organic Peroxides:* Materials that are normally stable, even under fire conditions and will not react with water. *Explosives:* Substances that are Non-Explosive. *Unstable Compressed Gases:* No Rating. *Pyrophorics:* No Rating. *Oxidizers:* No "0" rating allowed. *Unstable Reactives:* Substances that will not polymerize, decompose, condense or self-react.); 1 (Water Reactivity: Materials that change or decompose upon exposure to moisture. *Organic Peroxides:* Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy. *Explosives:* Division 1.5 and 1.6 substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases:* Pressure below OSHA definition. *Pyrophorics:* No Rating. *Oxidizers:* Packaging Group III; *Solids:* any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. *Liquids:* any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. *Unstable Reactives:* Substances that may decompose, condense or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosive hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors.); 2 (Water Reactivity: Materials that may react violently with water. *Organic Peroxides:* Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. *Explosives:* Division 1.4 -Ex plosive substances where the explosive effect are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. *Compressed Gases:* Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics:* No Rating. *Oxidizers:* Packaging Group II *Solids:* any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. *Liquids:* any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. *Unstable Reactives:* Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature); 3 (Water Reactivity: Materials that may form explosive reactions with water. *Organic Peroxides:* Materials that are capable of detonation or explosive reaction, but require a strong initiating source, or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives:* Division 1.2 - Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases:* Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics:* No Rating. *Oxidizers:* Packaging Group I *Solids:* any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture. *Liquids:* Any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives:* Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a moderate potential to cause significant heat generation or explosion.);

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): 4 (Water Reactivity: Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides:* Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives:* Division 1.1 and 1.2-explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases:* No Rating. *Pyrophorics:* Add to the definition of Flammability "4". *Oxidizers:* No "4" rating. *Unstable Reactives:* Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a high potential to cause significant heat generation or explosion.);

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: 0 Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC₅₀ for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC₅₀ for acute inhalation toxicity greater than 200 mg/L. Materials with an LD₅₀ for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD₅₀ for acute oral toxicity greater than 2000 mg/kg. Materials essentially non-irritating to the respiratory tract, eyes, and skin. 1 Materials that, under emergency conditions, can cause significant irritation. Gases and vapors with an LC₅₀ for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC₅₀ for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD₅₀ for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD₅₀ for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. 2 Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC₅₀ for acute inhalation toxicity greater than 3,000 ppm but less than or equal to 5,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an LC₅₀ for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD₅₀ for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. *Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators. Materials that are primary skin irritants or sensitizers. Materials whose LD₅₀ for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. Dusts and mists with an LC₅₀ for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD₅₀ for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD₅₀ for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. 3 (materials that, under emergency conditions, can cause serious or permanent injury): Gases and vapors whose LC₅₀ for acute inhalation toxicity is greater than 1,000 ppm but less than or equal to 3,000 ppm. Dusts and mists whose LC₅₀ for acute inhalation toxicity is greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials whose LD₅₀ for acute dermal toxicity is greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials whose LD₅₀ for acute oral toxicity is greater than 5 mg/kg but less than or equal to 50 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. *Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials that are respiratory irritants. Cryogenic gases that cause frostbite and irreversible tissue damage. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials that are corrosive to the skin. 4 (materials that, under emergency conditions, can be lethal): Gases and vapors whose LC₅₀ for acute inhalation toxicity less than or equal to 1,000 ppm. Dusts and mists whose LC₅₀ for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD₅₀ for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD₅₀ for acute oral toxicity is less than or equal to 5 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 1000 ppm.**

FLAMMABILITY HAZARD: 0 Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand; Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D. 1 Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur. Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D. Liquids, solids and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendation on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85 percent by weight. Liquids that have no fire point when tested by ASTM D 92 Standard Test Method for Flash and Fire Points by Cleveland Open Cup, up to a boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed up flash point of the solvent. Most ordinary combustible materials. 2 Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air; Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.)

DEFINITIONS OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): 2 (continued): Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures in air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. 3. Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that, on account of their physical form or environmental conditions, can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with a representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. 4. Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily: Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite when exposed to air. Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

INSTABILITY HAZARD: 0 Materials that in themselves are normally stable, even under fire conditions: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. 1. Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL. 2. Materials that readily undergo violent chemical change at elevated temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100 W/mL. 3. Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. 4. Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures.

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the National Fire Protection Association (NFPA). **Flash Point** - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air. **Autoignition Temperature**: The minimum temperature required to initiate combustion in air with no other source of ignition. **LEL** - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. **UEL** - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD₅₀** - Lethal Dose (solids and liquids) which kills 50% of the exposed animals; **LC₅₀** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** - concentration expressed in parts of material per million parts of air or water; **mg/m³** - concentration expressed in weight of substance per volume of air; **mg/kg** - quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include **TDL₀**, the lowest dose to cause a symptom and **TCL₀** the lowest concentration to cause a symptom; **TD₀**, **LDL₀**, and **LD₀**, or **TC**, **TC₀**, **LCL₀**, and **LC₀**, the lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** The sources are: **IARC** - the International Agency for Research on Cancer; **NTP** - the National Toxicology Program, **RTECS** - the Registry of Toxic Effects of Chemical Substances, **OSHA** and **CALJOSHA**. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** **BEI** - ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

REPRODUCTIVE TOXICITY INFORMATION:

A **mutagen** is a chemical which causes permanent changes to genetic material (DNA) such that the changes will propagate through generational lines. An **embryotoxin** is a chemical which causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A **teratogen** is a chemical which causes damage to a developing fetus, but the damage does not propagate across generational lines. A **reproductive toxin** is any substance which interferes in any way with the reproductive process.

ECOLOGICAL INFORMATION:

EC is the effect concentration in water. **BCF** = Bioconcentration Factor, which is used to determine if a substance will concentrate in lifeforms which consume contaminated plant or animal matter. **TL_m** = median threshold limit, Coefficient of Oil/Water Distribution is represented by **log K_{ow}** or **log K_{oc}** and is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

U.S. and CANADA:

ACGIH: American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (**OSHA**). **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively. **Superfund Amendments and Reauthorization Act (SARA)**; the Canadian Domestic/Non-Domestic Substances List (**DSL/NDL**); the U.S. Toxic Substance Control Act (**TSCA**); Marine Pollutant status according to the **DOT**; the Comprehensive Environmental Response, Compensation, and Liability Act (**CERCLA** or **Superfund**); and various state regulations. This section also includes information on the precautionary warnings which appear on the material's package label. **OSHA** - U.S. Occupational Safety and Health Administration.

EUROPEAN and INTERNATIONAL:

The **DFG**: This is the Federal Republic of Germany's Occupation Health Agency, similar to the U.S. OSHA. **EU** is the European Community (formerly known as the **EEC**, European Economic Community). **EINECS**: This is the European Inventory of Non-Existing Chemical Substances. The **ARD** is the European Agreement Concerning the International Carriage of Dangerous Goods by Road and the **RID** are the International Regulations Concerning the Carriage of Dangerous Goods by Rail.

~Verified on 2012-11 by Henry Schein to be the most current version of the MSDS. To be verified again on 2015-11. ~