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. IDENTIFICATION OF THE SUBSTANCE/MIXTURE

IDENTIFICATION of the SUBSTANCE or PREPARATION:

TRADE NAME:		**PROAIR® HFA (albuterol sulfate) Inhalation Aerosol** **PROAIR® RESPICLICK (albuterol sulfate) Inhalation Powder**
CHEMICAL NAME:	For Active Ingredient:	α_1 [(tert-butylamino) methyl]-4-hydroxy-m-xylene-α, α'-diol sulfate (2:1) (salt)
THERAPEUTIC CLASS:		$Beta_2$-Adrenergic Bronchodilator.
HOW SUPPLIED:		Inhalers containing active ingredient.
RELEVANT USE of the SUBSTANCE		Pharmaceutical for Human Use
USES ADVISED AGAINST:		Other than Relevant Use

COMPANY/UNDERTAKING IDENTIFICATION:

U.S. SUPPLIER/MANUFACTURER'S NAME:	**TEVA**
ADDRESS:	1090 Horsham Road North Wales, PA 19454
BUSINESS PHONE:	215-591-3000 [08:00 AM --> 05:00 PM]
EUROPEAN CONTACT:	**TEVA/TAPI**
ADDRESS:	Sicor sri-Via Terrazzano 77-20017 Cho (MI), Italy
BUSINESS PHONE:	+39 02 93197 306 [08:00 AM --> 05:00 PM]
EMERGENCY PHONE:	United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]
EMAIL:	TevaSDSRequest@tevapharm.com
DATE OF PREPARATION:	February 25, 2015
DATE OF REVISION:	New

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This material has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The material 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 excepted 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 an inhaler containing either a solution delivered by a non-flammable gas for PROAIR® HFA, or a powder delivered mechanically for PROAIR® RESPICLICK. **Health Hazards:** Inhalation of high quantity may be harmful. Skin and eye contact may cause irritation. Ingestion is not a likely route of exposure. The most common adverse effects from therapeutic use of this product include headache, tachycardia, pain, dizziness, pharyngitis, and rhinitis. Other possible effects include chest pain, infection, diarrhea, glossitis, accidental injury (nervous system), anxiety, dyspnea, ear disorder, ear pain, and urinary tract infection. Immediate hypersensitivity reactions may occur after administration of Albuterol Sulfate, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, anaphylaxis, and oropharyngeal edema. The active ingredient is a suspect reproductive toxin. These effects may be possible as a result of workplace exposure. Refer to Section 11 (Toxicological Information) for additional information on adverse effects. **Flammability Hazards:** If containers are heated or punctured, rupture may occur, and may cause injury 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 and nitrogen oxides, and fluorinated hydrocarbons for PROAIR® HFA). **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, PROAIR® HFA 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.

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-3,5dimethyl-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 FOR PROAIR® HFA				
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
EXCIPIENTS FOR PROAIR® RESPICLICK				
Lactose Monohydrate	5989-81-1	200-559-2	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.

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 OR EYE EXPOSURE: Flush affected area with water for 20 minutes.

INHALATION: Remove victim to fresh air if aerosols or dusts are inhaled.

INGESTION: CALL PHYSICIAN OR POISON CONTROL CENTER. Give victim up to three glasses of water. Do not induce vomiting.

INJECTION: Not a likely route of exposure.

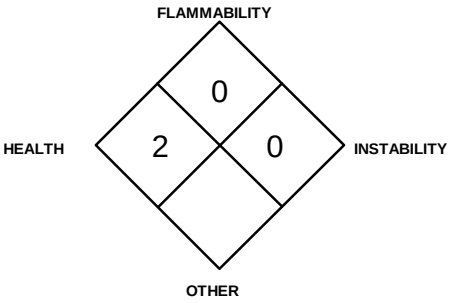
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing cardiovascular insufficiency, asthma, diabetes mellitus, preexisting asthma and those disorders to target organs described in Section 11 may be aggravated upon exposure to this product.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. As with all sympathomimetic aerosol medications, cardiac arrest and even death may be associated with acute inhalation exposure of Albuterol Sulfate. Treatment consists of 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.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not flammable.
AUTOIGNITION TEMPERATURE: Not available for product.
FLAMMABLE LIMITS (in air by volume, %): Not available for product.
FIRE EXTINGUISHING MEDIA: Water spray, 'ABC' extinguishers, carbon dioxide, foam, dry chemical and halon extinguishers.
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.
SPECIAL HAZARDS ARISING FROM THE SUBSTANCE: Containers of this product may rupture in heat of fire. This product must be substantially pre-heated before ignition can occur. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides and fluorinated hydrocarbons for PROAIR® HFA).
Explosion Sensitivity to Mechanical Impact: Not applicable.
Explosion Sensitivity to Static Discharge: May be sensitive.
SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Firefighters are recommended to wear Self-Contained Breathing Apparatus and full protective equipment. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING



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

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Spill kits should be kept in or near material handling areas. Avoid generating airborne aerosols or dusts of this product during spill response procedures.
PROTECTIVE EQUIPMENT:

Small Spills:	Nitrile or other appropriate gloves, labcoat or other protective clothing and eye protection for damaged inhalers.
Large Spills:	Double nitrile or other appropriate gloves, protective clothing (i.e., disposable Tyvek coveralls) and eye/face protection. When there is any danger of airborne aerosols being generated, use a full-face respirator equipped with a High Efficiency Particulate (HEPA) filter or Self-Contained Breathing Apparatus (SCBA).

METHODS FOR CLEAN-UP AND CONTAINMENT:

Small Spills:	For damaged inhalers, clean with wet absorbent pads and dispose of properly. Decontaminate the spill area using a bleach and detergent solution and rinse with clean water.
Large Spills:	Restrict access to the spill areas. Clean with wet absorbent pads and dispose of properly. Decontaminate the spill area using a bleach and detergent solution and rinse with clean water. Do not apply chemical in-activators as they may produce hazardous by-products.
All Spills:	Place all spill residues in an appropriate, labeled container and seal. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered material and report spill per regulatory requirements.

ENVIRONMENTAL PRECAUTIONS: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.
REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup.

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

7. HANDLING and STORAGE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this material should be thoroughly trained to handle it safely. Do not eat or drink while handling this material. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection).
CONDITIONS FOR SAFE STORAGE: Containers of this material must be properly labeled. Recommended Storage Temperature: 15-25°C (59-77°F). Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.
SPECIFIC END USE(S): This is a human pharmaceutical.
PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear appropriate personal protective equipment.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:
VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used.
WORKPLACE EXPOSURE LIMITS/CONTROL PARAMETERS: There are no occupational exposure limits for this product. Exposure limits for the active ingredient or excipients are available from Teva.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

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 CFR1910.132), *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: None needed for normal handling of this product. For large spill response or tasks involving generation of aerosols, use the appropriate Self-Contained Breathing Apparatus (SCBA) pressure-demand or other positive-pressure mode.

EYE PROTECTION: Wear splash goggles or safety glasses as appropriate for the task.

HAND PROTECTION: Wear nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response.

SKIN PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.).

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product as a whole.

PHYSICAL FORM: Inhaler with solution or powder.
ODOR: Ethereal for PROAIR® HFA; odorless for PROAIR® RESPICLICK.
MOLECULAR WEIGHT: Mixture.
MOLECULAR FORMULA: Mixture.
HOW TO DETECT THIS SUBSTANCE (identification/warning properties): The appearance may be a distinguishing characteristic of this product in event of accidental release.

The following information is for the active ingredient.

FORM: Crystalline powder.
COLOR: White.
MOLECULAR WEIGHT: 576.7
MOLECULAR FORMULA: $(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
FLASH POINT: Not available
MELTING POINT: 230-235°C (446-455°F).
SOLUBILITY IN WATER: Soluble.
OTHER SOLUBILITIES: Slightly soluble in ethanol.
COEFFICIENT OF OIL/WATER DISTRIBUTION (PARTITION COEFFICIENT): Log Kow: 0.64

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Normally stable.
DECOMPOSITION PRODUCTS: *Combustion:* Products of thermal decomposition may include carbon and nitrogen oxides and fluorinated hydrocarbons for PROAIR® HFA. *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 expected routes of occupational exposure to this product are via inhalation of aerosols or dusts, eye and skin contact. Exposure may cause allergic reaction. Exposure may also cause effects described under 'Other Potential Health Effects'.

INHALATION: Inhalation may be harmful and 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 irritate the nose and upper respiratory system. Symptoms may include sneezing, coughing, and nasal congestion.
CONTACT WITH SKIN or EYES: Mild irritation possible. Symptoms may include itching and redness and swelling. Eye irritation would be immediate.
SKIN ABSORPTION: No information.
INGESTION: Not a likely route of exposure.
INJECTION: Not a likely route of exposure.

OTHER HEALTH HAZARDS: In event that rupture occurs of a large quantity of PROAIR® HFA 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.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

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

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)

OTHER POTENTIAL HEALTH EFFECTS: In therapeutic use, the most common adverse effects from therapeutic use of this product include headache, tachycardia, pain, dizziness, pharyngitis, and rhinitis. Other possible effects include chest pain, infection, diarrhea, glossitis, accidental injury (nervous system), anxiety, dyspnea, ear disorder, ear pain, and urinary tract infection. Immediate hypersensitivity reactions may occur after administration of Albuterol Sulfate, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, anaphylaxis, and oropharyngeal edema. The active ingredient is a suspect reproductive toxin. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known. More details can be obtained from Teva.

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

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

Chronic: 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: It is anticipated that for Occupational Exposure the target organs are:

Acute: Eyes, skin, respiratory system.

Chronic: Skin.

TOXICITY DATA: Contact Teva for specific toxicity details on the active ingredient or any of the excipients.

CARCINOGENIC POTENTIAL OF COMPONENTS: Animal studies were inconclusive for tumorigenicity. The component found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH for PROAIR® HFA include:

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.)

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

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

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of this product in pregnant women; however, this product may cause fetal harm when administered to a pregnant woman pre-labor. In the workplace, the risk to the fetus should be communicated and the appropriate action should be taken to prevent exposure in accordance with company policy and regulatory requirements. This product is rated by the FDA for therapeutic risk as Pregnancy Risk Category C (refer to Definition of Terms for full category definitions).

Mutagenicity: Albuterol Sulfate was not mutagenic. The mutagenicity of Ethanol in PROAIR® HFA has been extensively studied.

Embryotoxicity/Teratogenicity: Various congenital anomalies, including cleft palate and limb defects, have been reported in the offspring of patients being treated with Albuterol. The harmful effects of the Ethanol component of PROAIR® HFA in pregnant animals are well documented.

Reproductive Toxicity: Reproduction studies in rats demonstrated no evidence of impaired fertility for oral doses of Albuterol Sulfate. It is not known whether Albuterol Sulfate is excreted in breast milk. Because of the potential for adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

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: Currently, there is no specific information available on the potential mobility of this product.

PERSISTENCE AND BIODEGRADABILITY: Currently, there is no specific information. Some biodegradation is expected.

BIO-ACCUMULATION POTENTIAL: Currently, no specific information is available. Active ingredient expected to bio-accumulate.

ECOTOXICITY: This material may be harmful to contaminated plant and animal life, especially in large quantities. All releases to terrestrial, atmospheric and aquatic environments should be avoided. No aquatic toxicity data are available for the active ingredient.

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.

OTHER ADVERSE EFFECTS: The 1,1,1,2-Tetrafluoroethane component of PROAIR® HFA has been atmospherically modeled for its impact on depleting ozone and as a contributor to global warming.

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 protective clothing, 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. 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. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters. Reusable equipment should be cleaned with soap and water and thoroughly rinsed.

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.

EWC 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' applies to PROAIR® HFA.

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 for PROAIR® HFA, 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 for PROAIR® HFA.

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 for PROAIR® HFA 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/NDSL 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 for PROAIR® HFA has CEPA Reporting Requirements as a Greenhouse gas subject to mandatory reporting by June 1, 2008

15. REGULATORY INFORMATION (Continued)

ADDITIONAL CANADIAN REGULATIONS (continued):

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/EEC[4], as amended and applicable at the data 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. 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. Avoid contact with skin, eyes, and clothing. Keep container closed. Use gloves, safety glasses, and appropriate respiratory and body protection.

FIRST-AID: If exposed, seek immediate medical attention. If swallowed, do not induce vomiting; give victim up to three glasses of water. In case of contact, immediately flush skin with copious amounts of warm water for 20 minutes. If inhaled, remove to fresh air. If not breathing, give artificial respiration or oxygen if necessary.

IN CASE OF FIRE: Use water fog, dry chemical or CO_2, or alcohol foam.

IN CASE OF SPILL: Refer to Safety Data Sheet for complete spill response procedures. Spill response should be performed by persons properly trained to do so. Decontaminate area with bleach and detergent solution and triple rinse area. Place spill debris in a suitable container.

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.

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.

For PROAIR® HFA: 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.

For PROAIR® HFA: 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.

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.

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