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:	**ACITRETIN CAPSULES**
CHEMICAL NAME: Active Ingredient:	all-trans-9-(4-methoxy-2,3,6-trimethylphenyl)-3,7-dimethyl-2,4,6,8-nonatetraenoic acid
CHEMICAL CLASS:	Retinoid
THERAPEUTIC CLASS:	Anti-psoriasis
RELEVANT USE of the SUBSTANCE:	Human Pharmaceutical
HOW SUPPLIED:	10 mg light green cap and white body capsule; 17.5 mg yellow cap and yellow body capsule; 25 mg light green cap and yellow body capsule.

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:	January 23, 2015
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 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 a two-piece capsule filled with yellow powder in the following colors: light green cap and white body (10 mg), yellow cap and yellow body (17.5 mg), and light green cap and yellow body (25 mg). **Health Hazards:** This product contains a known human teratogen. In the workplace, exposure to dusts from product via inhalation and skin contact may cause irritation. Eye contact from dusts can cause mechanical irritation. Non-therapeutic ingestion may be harmful. In therapeutic use, the most common adverse effects reported include headache and vertigo. Adverse effects on the eyes, pancreas, liver, kidneys and cardiovascular, skeletal and nervous systems have been reported. Exposure may cause sensitivity to UV light and sun light, resulting in sunburn burn. Reports of depression and other psychological effects have occurred, as well as serious adverse skin reactions and adverse effects on the liver. Exposure during pregnancy will harm to fetus. 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:** This product is combustible and can ignite if highly heated or if exposed to direct flame. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** May cause harm to aquatic organisms if accidentally released. All environmental release should be avoided. **Emergency Recommendations:** Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/v	EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
ACTIVE INGREDIENTS				
Acitretin all-trans-9-(4-methoxy-2,3,6-trimethylphenyl)-3,7-dimethyl-2,4,6,8-nonatetraenoic acid	55079-83-9	259-474-4	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Reproductive Toxicity Cat. 2, Reproductive Toxicity Cat. 3, Irritant, Dangerous for the Environment Risk Phrase Codes: R61, R62, R36/37/38, R50/53 Hazard Symbols: T, Xi, N GHS and EU 1272/2008 Classification: Reproductive Toxicity Cat. 1B, Skin Irritation Cat. 2, Eye Irritation Cat. 2B, STOT (Inhalation-Respiratory System) SE Cat. 3, Acute Oral Toxicity Cat. 5, Aquatic Acute Toxicity Cat.1 Hazard Codes: H360D, H315, H319, H335, H303, H410 Hazard Symbol/Pictogram: GHS07, GHS08, GHS09
EXCIPIENTS				
Crospovidone	9003-39-8	Not Listed	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable
Gelatin	9000-70-8	232-554-6	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Microcrystalline Cellulose	9004-34-6	232-674-9	Proprietary	EU 67/54: Classification: Not applicable. GHS & EU 1272/2008 Classification: Not applicable.
Poloxamer	9003-11-6	Not Listed	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Sodium Ascorbate	134-3-2	205-126-1	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Sodium Lauryl Sulfate	151-21-3	205-788-1	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Harmful, Irritant Risk Phrases: R22, R36 Hazard Symbols: Xn GHS & EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Eye Irritation Cat. 2A Hazard Codes: H302, H319 Hazard Symbol/Pictogram: GHS07
Titanium Dioxide	13463-67-7	236-675-7	Proprietary	SELF-CLASSIFICATION EU 67/548 Classification: Carcinogenic Cat. 3 Risk Phrase Codes: R40 Hazard Symbols: Xn GHS and EU 1272/2008 Classification: Carcinogenic Cat. 2 Hazard Codes: H351 Hazard Symbol/Pictogram: GHS08

Note: Pigments are in colored capsules that are not listed and do not affect hazards for the purpose of this SDS. 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 dusts are inhaled.

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

INJECTION: Not likely route of exposure.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing severely impaired renal, liver or kidney function, hepatitis, increased intracranial pressure and in patients with chronic abnormally elevated blood lipid values, 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. Persons developing hypersensitivity reactions should receive medical attention.

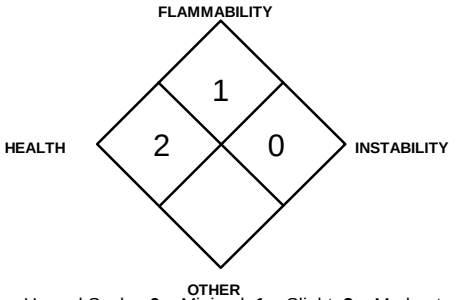
5. FIRE-FIGHTING MEASURES

FLASH POINT: Not available.
AUTOIGNITION TEMPERATURE: Not available.
FLAMMABLE LIMITS (in air by volume, %): Not applicable.
FIRE EXTINGUISHING MEDIA: All types acceptable.
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.
SPECIAL HAZARDS ARISING FROM THE SUBSTANCE: 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).

Explosion Sensitivity to Mechanical Impact: Not applicable.
Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Firefighters must 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 of this product during spill response procedures.

PROTECTIVE EQUIPMENT:

Small Spills: Nitrile or other appropriate gloves, labcoat or other protective clothing and eye protection.

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: 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: 20-25°C (68-77°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 is for the product:

PHYSICAL FORM: Two-piece capsules, filled with white spheres.
COLOR: As described in Section 2.
ODOR: Practically odorless.
ODOR THRESHOLD: Not applicable.
MOLECULAR WEIGHT: Mixture.
MOLECULAR FORMULA: Mixture.
HOW TO DETECT THIS PRODUCT (identification/warning properties): The appearance may be a distinguishing characteristic of this product in event of accidental release.

The following is for the active ingredient:

FORM: Crystalline solid.
COLOR: Yellow to greenish-yellow.
MOLECULAR WEIGHT: 326.44
MOLECULAR FORMULA: $C_{21}H_{26}O_3$
ODOR: Odorless.
ODOR THRESHOLD: Odorless.
BOILING POINT @ 760 mmHg: 521.3°C (970.3°F) [est.]
MELTING POINT: 228-230°C (442-446°F)
VAPOR PRESSURE (air = 1) @ 25°C: 0.0 mmHg [predict.]
SPECIFIC GRAVITY (water = 1): 1.052 g/cm^3
FLASH POINT: 180.3°C (356.5°F) [est.]
DECOMPOSITION TEMPERATURE: Not available.
SOLUBILITY IN WATER @ 25°C: Insoluble (0.0726 mg/L).
OTHER SOLUBILITIES: Slightly soluble in acetone and in alcohol, very slightly soluble in cyclohexane.
COEFFICIENT WATER/OIL DISTRIBUTION: Log Kow = 6.40; Log P(oct) = 5.7 (est.)

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Stable under normal conditions. May be light sensitive.
DECOMPOSITION PRODUCTS: *Combustion:* Products of thermal decomposition may include carbon and nitrogen oxides.
Hydrolysis: None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Incompatible with strong oxidizing agents.
POSSIBILITY OF HAZARDOUS REACTION/POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Exposure to or contact with extreme temperatures, 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 dusts, eye and skin contact. Exposure may also cause effects described under 'Other Potential Health Effects'.

INHALATION: Dusts may 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.

SKIN ABSORPTION: No information on this active ingredient; similar retinoids have displayed absorption potential.

INGESTION: May be harmful. May irritate the mouth, throat, and gastrointestinal system.

INJECTION: Not a likely route of exposure.

OTHER POTENTIAL HEALTH EFFECTS: In therapeutic use, the most common effects have included headache and vertigo. Adverse effects on the eyes, pancreas, liver, kidneys and cardiovascular, skeletal and nervous systems have been reported. Exposure may cause sensitivity to UV light and sun light, resulting in sunburn burn. Reports of depression and other psychological effects have occurred, as well as serious adverse skin reactions and adverse effects on the liver. Exposure during pregnancy will harm to fetus. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known.

11. TOXICOLOGICAL INFORMATION

OTHER POTENTIAL HEALTH EFFECTS (continued): Body systems adversely affected during therapeutic use are provided below. More details are also available from Teva.

- ***Body as a Whole***
- ***Cardiovascular System***
- ***Gastrointestinal System***
- ***Eyes***
- ***Liver & Biliary Systems***
- ***Musculoskeletal***
- ***Mucous Membranes***
- ***Nervous***
- ***Psychiatric***
- ***Skin and Appendages***
- ***Respiratory System***

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: Dusts from product may cause irritation if inhaled and in contact with skin or eyes. Accidental ingestion may be harmful.

Chronic: Can cause harm to fetus; contains material known to be a human teratogen. Dermatitis (inflammation and redness of the skin) may occur after chronic, low-level skin contact. Chronic exposure to this product may cause adverse effects as described under 'Other Potential Health Effects'. No other chronic effects have been reported from workplace exposure.

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

Acute: Eyes, skin, respiratory system.
Chronic: Fetal harm.

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

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2
FLAMMABILITY HAZARD	(RED)	1
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

CARCINOGENIC POTENTIAL OF COMPONENTS: There are no reports of carcinogenic effects in humans. The components found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH are as follows::

CROSPOVIDONE: IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

TITANIUM DIOXIDE: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-2B (Possibly Carcinogenic to Humans); MAK-3A (Substances Which Cause Concern that They Could Be Carcinogenic for Man But Cannot Be Assessed Conclusively Because of Lack of Data. Substances for which the criteria for classification in Category 4 or 5 are fulfilled, but for which the database is insufficient for the establishment of a MAK value.); NIOSH-Ca (Potential Occupational Carcinogen with No Further Categorization)

IRRITANCY OF PRODUCT: Inhalation of dusts from this product may be irritating to the respiratory system. Dusts will also be irritating to the skin and eyes.

SENSITIZATION TO THE PRODUCT: Exposure to this product may cause sensitization to UV light and the sun, resulting in sunburn.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of in pregnant women; however, Acitretin can cause fetal harm when administered to a pregnant woman. 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 X (refer to Definition of Terms for full category definitions).

Mutagenicity: No evidence of mutagenicity of Acitretin was demonstrated in assays.

Embryotoxicity/Teratogenicity: Acitretin is teratogenic in humans and is contraindicated during pregnancy.

Reproductive Toxicity: No evidence of adverse fertility effects in animal studies. It is unknown if the active ingredient is excreted in human milk. Because of the potential for serious 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: This product has not been tested for mobility in soils.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence and biodegradability. No predicted values are available.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential.

ECOTOXICITY: This product may be harmful or fatal to contaminated plant and animal-life (especially if large quantities are released). This product has not been tested for aquatic toxicity. No aquatic toxicity data are available for components of this product.

OTHER ADVERSE EFFECTS: The components of this product are not listed as having ozone depletion potential.

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.
U.S. EPA WASTE NUMBER: Not applicable.
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 NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.
TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This material does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada.
INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.
INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.
EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.
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) and is not 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: No
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): As a retinol/retinyl ester, the active ingredient is on the California Proposition 65 lists. WARNING. The active ingredient in this product is known to the State of California to cause developmental harm.
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 components of this product are not on the CEPA Priority Substances Lists.
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.

15. REGULATORY INFORMATION (Continued)

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.

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!** CONTAINS KNOWN HUMAN TERATOGEN. MAY CAUSE RESPIRATORY SYSTEM, EYE, AND SKIN IRRITATION. MAY BE HARMFUL IF SWALLOWED. MAY CAUSE ADVERSE EYE, EAR, NERVOUS OR GASTROINTESTINAL SYSTEM EFFECTS. CONTAINS MATERIAL THAT CAN CAUSE HARM TO AQUATIC ORGANISMS.. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES.

Do not taste or swallow. 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:

Acitretin: This is a self-classification.
- Classification: Reproductive Toxicity Category 1B, Skin Irritation Category 2, Eye Irritation Category 2B, Specific Target Organ Toxicity (Inhalation-Respiratory System) Single Exposure Category 3, Acute Oral Toxicity Category 5, Aquatic Acute Toxicity Category 1, Aquatic Chronic Toxicity Category 1
- Hazard Statement Codes: H360D: May damage the unborn child. H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation. H303: May be harmful if swallowed. H410: Very toxic to aquatic life with long-lasting effects.

Sodium Lauryl Sulfate: This is a self-classification.
- Classification: Acute Oral Toxicity Category 4, Eye Irritation Category 2A
- Hazard Statements: H302: Harmful if swallowed. H319: Causes serious eye irritation.

Titanium Dioxide: This is a self-classification.
- Classification: Carcinogenic Category 2
- Hazard Statements: H351: Suspected of causing cancer.

All Other Components: No classification has been published or is applicable.

Full Text EU 67/548/EEC:

Acitretin: This is a self-classification.
- Classification: Reproductive Toxicity Category 2, Reproductive Toxicity Category 3, Irritant, Dangerous for the Environment
- Risk Phrases: R61: May cause harm to the unborn child. R36/37/38: Irritating to eyes, respiratory system and skin. R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Sodium Lauryl Sulfate: This is a self-classification.
- Classification: Harmful, Irritant
- Risk Phrases: R22: Harmful if swallowed. R36: Irritating to eyes.

Titanium Dioxide: This is a self-classification.
- Classification: Carcinogenic Category 3
- Risk Phrases: R40: Limited evidence of a carcinogenic effect.

All Other Components: No classification has been published or is applicable.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Criteria of the GHS and CLP 1272: 2008 were used for classification.

PREPARED BY: Teva Pharmaceuticals, Inc., EHS Department (215) 591-3000
DATE OF PRINTING: January 23, 2015
REVISION HISTORY: New.