PART I  What is the material and what do I need to know in an emergency?

1. PRODUCT IDENTIFICATION

TRADE NAME/MATERIAL NAME: Zinc Oxide Ointment

DESCRIPTION: Zinc Oxide Ointment
NDC #: 0168-0062-02, 0168-0062-16, 0168-0062-31
CHEMICAL NAME (for active ingredient): Zinc Oxide
CHEMICAL FAMILY (for active ingredient): Zinc Compound
HOW SUPPLIED: Ointment
FORMULA (for active ingredient): ZnO
PRODUCT USE: Pharmaceutical for Human Use
SUPPLIER/MANUFACTURER’S NAME: FOUGERA PHARMACEUTICALS, INC.
ADDRESS: 60 Baylis Road
Melville, NY 11747
BUSINESS PHONE/GENERAL MSDS INFORMATION: 1-631-454-7677
EMERGENCY PHONE (U.S./Canada/Puerto Rico): 1-800-424-9300 (24-hrs)
EMERGENCY PHONE (OUTSIDE U.S.): + 1-631-454-7677

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, and Canadian WHMIS [Controlled Products Regulations] required information is included in appropriate sections based on the U.S. ANSI Z400.1-2004 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: This product is a white ointment with a petroleum jelly odor. Health Hazards: The chief health hazard associated with exposure during normal use and handling is the potential for mild irritation of contaminated skin. Individuals who have had allergic reactions to products containing the active ingredient, Zinc Oxide, or any other components of this product may experience allergic reactions to this product. Flammability Hazards: This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and zinc compounds). Reactivity Hazards: This product is not reactive. Environmental Hazards: This product has not been tested for environmental effects. Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc Oxide</td>
<td>1314-13-2</td>
<td>20%</td>
</tr>
<tr>
<td>White Wax (Beeswax)</td>
<td>8006-40-4</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>8042-47-5</td>
<td>Proprietary</td>
</tr>
<tr>
<td>White Petrolatum</td>
<td>8009-03-8</td>
<td>Proprietary</td>
</tr>
</tbody>
</table>

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

4 FIRST-AID MEASURES

Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and MSDS to physician or health professional with the contaminated individual.

SKIN EXPOSURE: If adverse skin effects occur, discontinue use. Seek medical attention.

EYE EXPOSURE: If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

INHALATION: If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

INGESTION: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin conditions may be aggravated by repeated overexposures to this product.

RECOMMENDATIONS TO PHYSICIANS: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.
5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.
AUTOIGNITION TEMPERATURE: Not established.
FLAMMABLE LIMITS (in air by volume, %): Not applicable.
FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.
SPECIAL FIRE AND EXPLOSION HAZARDS: This product is combustible.
When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and zinc compounds).
Explosion Sensitivity to Static Discharge: Not sensitive.
ADVICE TO FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

SPILL AND LEAK RESPONSE: Proper protective equipment should be used. In the event of a spill, clear the area and protect people. 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).
Small Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.
Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Dispersing mists or sprays into surrounding air and possibly inhaling them is a serious matter and should be treated as such. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus. Absorb spilled liquid using polypads or other suitable absorbent material. Prevent material from entering sewer or confined spaces, waterways, soil or public waters. 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. Decontaminate the spill area using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with Federal, State, and local procedures (see Section 13, Disposal Considerations).

PART III  How can I prevent hazardous situations from occurring?

7. HANDLING and USE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration.
STORAGE AND HANDLING PRACTICES: Employees must be trained to properly use this product. Use of this product should be performed in a designated area for working with drugs. Ensure product is properly labeled. Store this product away from incompatible materials. Store this product in original container.
PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.
SPECIFIC USE(S): This product is a human pharmaceutical. Follow all industry standards for use of this product.
PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad. Collect all rinsates and dispose of according to applicable U.S. Federal, State, and local hazardous waste disposal regulations or waste disposal regulations of Canada. All disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS.
8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/GUIDELINES:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EXPOSURE LIMITS IN AIR</th>
<th>ACGIH-TLVs</th>
<th>OSHA-PELs</th>
<th>NIOSH-RELs</th>
<th>NIOSH</th>
<th>OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
</tr>
<tr>
<td>Zinc Oxide (1314-13-2)</td>
<td>10 (resp. fraction)</td>
<td>15 (total dust), 5 (total dust) [vacated 1989 PEL]</td>
<td>NE</td>
<td>5 (dust only)</td>
<td>15 ceiling (15 min)</td>
<td>500</td>
<td>DFG MAKs: TWA = 0.1 (resp. fraction), 2 (inhalable fraction) PEAK = Respirable Fraction: 4•MAK 15 min. average value, 1-hr interval, 4 per shift; Inhalable Fraction: 2•MAK 15 min. average value, 1-hr interval, 4 per shift</td>
</tr>
<tr>
<td>Mineral Oil (8042-47-5)</td>
<td>5 (inhalable fraction)</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>White Wax (Beeswax) (8006-40-4)</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>White Petrolatum (8009-03-8)</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
</tbody>
</table>

NE = Not Established  See Section 16 for Definitions of Terms Used.

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) or equivalent standards of Canada (including CSA Standard Z94.4-02 and CSA Standard Z94.3-07). Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, or Canadian CSA Standard Z94.4-02. Oxygen levels below 19.5% are considered IDLH by 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 OSHA’s Respiratory Protection Standard (1910.134-1998).


HAND PROTECTION: For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff. If necessary, refer to U.S. OSHA 29 CFR 1910.138 or appropriate standards of Canada.

BODY PROTECTION: During patient administration, use of lightweight cotton gown or other medical attire is recommended. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee’s feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136 and the Canadian CSA Standard Z195-02, Protective Footwear.

9. PHYSICAL and CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOILING POINT</td>
<td>&gt; 121°C(250°F)</td>
</tr>
<tr>
<td>EVAPORATION RATE (nBuAc = 1)</td>
<td>0</td>
</tr>
<tr>
<td>FREEZING/MELTING POINT</td>
<td>Not established.</td>
</tr>
<tr>
<td>SOLUBILITY IN WATER</td>
<td>Insoluble.</td>
</tr>
<tr>
<td>VAPOR PRESSURE (air = 1)</td>
<td>1</td>
</tr>
<tr>
<td>SPECIFIC GRAVITY @20°C (water = 1)</td>
<td>1.01</td>
</tr>
<tr>
<td>ODOR THRESHOLD</td>
<td>Not established.</td>
</tr>
<tr>
<td>pH</td>
<td>Not established.</td>
</tr>
<tr>
<td>COEFFICIENT WATER/OIL DISTRIBUTION</td>
<td>Not established.</td>
</tr>
<tr>
<td>APPEARANCE AND COLOR</td>
<td>This product is a white ointment with a petroleum jelly odor.</td>
</tr>
<tr>
<td>HOW TO DETECT THIS SUBSTANCE</td>
<td>The appearance of this product can be a distinguishing characteristic to identify it in event of accidental release.</td>
</tr>
</tbody>
</table>

10. STABILITY and REACTIVITY

REACTIVITY/CHEMICAL STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: Combustion: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides and zinc compounds). Hydrolysis: None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

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

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees handling this product in an occupational setting. This product is designed for application on the skin. The following paragraphs describe the symptoms of exposure by route of exposure.
INHALATION: Although unlikely due to form of product, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Skin contact may cause mild irritation. Eye contact can cause temporary blurred vision.

SKIN ABSORPTION: The components of this product are not known to be absorbed through the skin.

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause nausea, vomiting, and diarrhea.

INJECTION: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection.

GENERAL TOXICITY INFORMATION: Persons using the product in therapeutic doses may experience temporary blurred vision and mild irritation.

IRRITANCY OF PRODUCT: This product may mildly to moderately irritate contaminated tissue.

SENSITIZATION OF PRODUCT: Individuals who have had allergic reactions to products containing the Zinc Oxide component of this product or any other components of this product may experience allergic reactions to this product.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Overexposure to this product may cause the following health effects:

Acute: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin. Accidental ingestion may cause nausea, vomiting, and diarrhea. Eye contact will cause temporary blurred vision.

Chronic: None known.

TARGET ORGANS:


Chronic: Occupational Exposure: Skin. Therapeutic Doses: Skin.

TOXICITY DATA: The toxicity data available for the active component of this product are presented in this MSDS. Additional data are available for the excipient components of this product, but are not presented in this MSDS; Contact Fougera for more information.

ZINC OXIDE: DNA Adduct (Escherichia coli) = 3000 ppm
Cytogenetic Analysis (inhalation, rat) = 100 µg/m²
Morphological Transformation (embryo, hamster) = 1 mg/L
Unscheduled DNA Synthesis (embryo, hamster) = 1 mg/L
Unscheduled DNA synthesis (inhalation, guinea pig) = 5300 µg/m³/3 hours/6 days
Sister Chromatid Exchange (embryo, hamster) = 300 µg/L
Standard Draize Test (eye, rabbit) = 500 mg/24 hours; mild
TCLo (inhalation, human) = 600 mg/m³; cough, dyspnea, other changes

Carcinogenic Information: The incipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

MINERAL OIL: IARC-3 (Not Classifiable as to Carcinogenicity to Humans)
ZINC OXIDE: EPA-II (Inadequate Information to Assess Carcinogenic Potential); EPA-D (Not Classifiable as to Carcinogenicity to Humans); EPA-I (Data are Inadequate for an Assessment of Carcinogenic Potential)

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 cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: Studies have not been performed to evaluate the mutagenic, embryotoxic, teratogenic or reproductive toxicity potential of this product.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, there are no ACGIH Biological Exposure Indices (BEIs) determined for 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 soil absorption or mobility.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability.

BIOACCUMULATION: This product has not been tested for bioaccumulation.

ECOTOXICITY: No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated terrestrial and aquatic plant and animal life, especially in large quantities.

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

OTHER ADVERSE EFFECTS: No component of this product is known to have ozone depletion potential.

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHODS: 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. 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. 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.

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada. This product, if unaltered by handling, 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. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS: This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

15. REGULATORY INFORMATION

UNITED STATES 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 any component of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

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

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

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The components of this product are not on the California Proposition 65 lists.

CANADIAN REGULATIONS:

CANADIAN DSL/NDSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is exempt from requirements of the DSL/NDSL Inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities 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.

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY CAUSE SKIN AND EYE IRRITATION. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration.
16. OTHER INFORMATION (Continued)

ANSI LABELING (continued): FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting-seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO₂, or “alcohol” foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Material Safety Data Sheet for additional information.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 888/869-4846
DATE OF PRINTING: February 1, 2012

A large number of abbreviations and acronyms appear on a MSDS. 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.

DFG MAK Germ Cell Mutagen Categories: 1: Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed humans. 2: Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed mammals. 3A: Substances that have been shown to induce genetic damage in germ cells of humans or 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 that 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 that are deemed mutagenic in vitro and structurally related to known in vivo mutagens. 4: Not applicable (Category 4 carcinogenic substances are those with no-genotoxic mechanisms of action. By definition, germ cell mutagens are genotoxic. Therefore, 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.

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: 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: 35339-35351 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 there is a danger of cutaneous absorption.

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

WEEL: Workplace Environmental Exposure Limits from the AHA.
HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

FLAMMABILITY HAZARD: 4 Severe Hazard: Materials that will rapidly or completely vaporize into flammable gases, mists, or aerosols at or below 70°C (158°F) and pressures at or below 0.18 MPa (25 psig) and that will burn with an explosion hazard greater than 0.5 mg/L. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) (73°F and below 37.8°C (100°F)).

PHYSICAL HAZARD: 0 Water Reactivity: Materials that do not react with water. 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 violently. Explosives: Division 1.5 & 1.6 explosives. 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: No 0 Rating. Dusts and mists with an LC50 for acute inhalation toxicity less than or equal to 10 mg/L.

DEFINITION OF TERMS (Continued):

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

HEALTH HAZARD: 1: None. 2: Material that is considered to be a respiratory irritant. Gases and mists with an LC50 for acute inhalation toxicity greater than 5,000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

HEALTH HAZARD: 2 (continued): Dusts and mists with an LC50 for acute inhalation toxicity less than or equal to 10 mg/L but less than or equal to 200 mg/L. Materials with an LC50 for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100W/mL.
NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

INSTABILITY HAZARD (continued): 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. Materials that are sensitive to localized thermal or mechanical shock 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.

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 vapor to form an ignitable mixture with air near the surface of the liquid or within the test vessel used. Autoignition Temperature: Minimum temperature of a solid, liquid, or gas required to initiate or cause self-sustained combustion in air with no other source of ignition. LEL: Lowest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame. UEL: Highest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame.

DEFINITION OF TERMS (Continued)

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. LD₅₀: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC₅₀: Lethal Concentration (gases) that 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. TDL₅₀: Lowest dose to cause a symptom. TCL₅₀: Lowest concentration to cause a symptom. TD₅₀, LD₅₀, and LDₐ₀: or TC, TC₅₀, LD₅₀, and LDₐ₀: Lowest dose (or concentration) to cause lethal or toxic effects.

TOXICOLOGICAL INFORMATION (continued):

Cancer Information: IARC: International Agency for Research on Cancer. NTP: National Toxicology Program. RTECS: Registry of Toxic Effects of Chemical Substances. 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 that causes permanent changes to genetic material (DNA) such that the changes will propagate through generation lines. An embryo toxin is a chemical that 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 that causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance that interferes in any way with the reproductive process.

ECOLOGICAL INFORMATION:

EC: Effect concentration in water. BCF: Bioconcentration Factor, which is used to determine if a substance will concentrate in life forms that consume contaminated plant or animal matter. TLm: Median threshold limit. log KOW or log KOC: Coefficient of Oil/Water Distribution is used to assess a substance’s behavior in the environment.

REGULATORY INFORMATION:

U.S.:

EPA: U.S. Environmental Protection Agency. ACGIH: American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits. OSHA: U.S. Occupational Safety and Health Administration. NIOSH: National Institute of Occupational Safety and Health, which is the research arm of OSHA. DOT: U.S. Department of Transportation. TC: Transport Canada. SARA: Superfund Amendments and Reauthorization Act. TSCA: U.S. Toxic Substance Control Act. CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act. Marine Pollutant status according to the DOT; CERCLA or Superfund; and various state regulations. This section also includes information on the precautionary warnings that appear on the material’s package label.

CANADA:

REVISION HISTORY

Date                Changes
December 21, 2011   Company name change correction. Change of heading text, Section 5. Review and up-date of exposure limits to current, Section 8. Change text on Reproductive Toxicity, Section 11. Revision to Definition of Terms. Up-date Section 12. Revise Canadian WHMIS status. Move ANSI Labeling to Section 16. Add revision history section.