



## SEMISYNTHETIC PACLITAXEL INJECTION, USP

### SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

#### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

##### Product Identifier

**Product name:** Semisynthetic Paclitaxel Injection, USP

##### Intended Use of the Product

**Use of the substance/mixture:** Pharmaceutical. Intravenous. Use only as directed. Refer to product insert for usage instructions and product information.

##### Name, Address, and Telephone of the Responsible Party

##### Supplier:

Mylan Institutional LLC  
1718 Northrock Court  
Rockford, IL 61103 USA  
1-888-258-4199

[www.mylan.com](http://www.mylan.com)

##### Manufacturer:

Agila Specialities Pvt. Ltd.  
A Mylan Company  
Opposite IIM, Bilekahalli  
Bangalore, India

##### Emergency Telephone Number

**Emergency number** : +1 877-446-3679

#### 2. HAZARDS IDENTIFICATION

**Patients/Consumers:** Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

##### Classification of the Substance or Mixture

##### Classification (GHS-US)

Flam. Liq. 2 H225  
Eye Irrit. 2A H319  
Skin Sens. 1 H317  
Repr. 2 H361

##### Label Elements

##### GHS-US labeling

**Hazard pictograms (GHS-US)** :



GHS02



GHS07



GHS08

**Signal word (GHS-US)** : Danger

**Hazard statements (GHS-US)** : H225 - Highly flammable liquid and vapor  
H317 - May cause an allergic skin reaction  
H319 - Causes serious eye irritation  
H361 - Suspected of damaging fertility or the unborn child

**Precautionary statements (GHS-US)** : P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P210 - Keep away from sparks, open flames, hot surfaces, heat - No smoking.  
P233+P240 - Keep container tightly closed. Ground/bond container and receiving equipment.  
P241 - Use explosion-proof ventilating, lighting, electrical equipment.  
P242+P243 - Use only non-sparking tools. Take precautionary measures against static discharge.  
P261 - Avoid breathing vapors, spray, mist.  
P264 - Wash hands, forearms, and exposed areas thoroughly after handling.

P272 - Contaminated work clothing should not be allowed out of the workplace.  
 P280 - Wear protective clothing, protective gloves, eye protection.  
 P302+P352 - IF ON SKIN: Wash with plenty of soap and water.  
 P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.  
 P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P308+P313 - If exposed or concerned: Get medical advice/attention.  
 P321 - Specific treatment (see Section 4).  
 P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
 P337+P313 - If eye irritation persists: Get medical advice/attention.  
 P362+P364 - Take off contaminated clothing and wash it before reuse.  
 P370+P378 - In case of fire: Use dry chemical powder, alcohol-resistant foam, carbon dioxide (CO<sub>2</sub>) to extinguish.  
 P403+P235+P405 - Store in a well-ventilated place. Keep cool. Store locked up.  
 P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

**Other Hazards** Not available

**Unknown acute toxicity (GHS-US)** Not available

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Mixture**

| Name          | Product identifier  | % (w/w)   | Classification (GHS-US)  |
|---------------|---------------------|-----------|--|
| Ethyl alcohol | (CAS No) 64-17-5    | 40 - 50   | Flam. Liq. 2, H225<br>Eye Irrit. 2A, H319  |
| Paclitaxel    | (CAS No) 33069-62-4 | 0.1 - 0.9 | Skin Irrit. 2, H315<br>Eye Dam. 1, H318<br>Skin Sens. 1, H317<br>Repr. 2, H361<br>STOT SE 3, H335<br>Aquatic Chronic 4, H413 |

Full text of H-phrases: see section 16

**4. FIRST AID MEASURES**

**Description of First Aid Measures**

**General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.

**Inhalation:** The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

**Skin Contact:** Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

**Eye Contact:** The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

**Ingestion:** Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

**Most Important Symptoms and Effects Both Acute and Delayed**

**General:** Please refer to the package insert for more detailed information. Causes serious eye irritation. Exposure may produce an allergic reaction.

**Inhalation:** Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

**Skin Contact:** May cause an allergic skin reaction.

**Eye Contact:** Causes serious eye irritation.

**Ingestion:** Ingestion is likely to be harmful or have adverse effects.

**Injection:** The most common side effects include: low blood counts, hair loss, arthralgias and myalgias, peripheral neuropathy, nausea and vomiting, diarrhea, mouth sores, hypersensitivity reaction.

**Chronic symptoms:** Suspected of damaging fertility or the unborn child.

**Indication of Any Immediate Medical Attention and Special Treatment Needed**

If exposed or concerned, get medical advice and attention. In the event of accidental injection, go immediately to the nearest emergency room.

**5. FIREFIGHTING MEASURES**

**Extinguishing Media**

**Suitable extinguishing media:** Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO<sub>2</sub>).

**Unsuitable extinguishing media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

### **Special Hazards Arising From the Substance or Mixture**

**Fire hazard:** Highly flammable liquid and vapor.

**Explosion hazard:** Heat may build pressure, rupturing closed containers, spreading fire and increasing risk of burns/injuries.

**Reactivity:** Reacts violently with (strong) oxidizers: (increased) risk of fire/explosion.

### **Advice for Firefighters**

**Precautionary measures fire:** Exercise caution when fighting any chemical fire.

**Firefighting instructions:** Use water spray or fog for cooling exposed containers.

**Protection during firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Carbon oxides (CO, CO<sub>2</sub>). Nitrogen compounds.

**Other information:** Refer to Section 9 for flammability properties.

## **6. ACCIDENTAL RELEASE MEASURES**

### **Personal Precautions, Protective Equipment and Emergency Procedures**

**General measures:** Avoid all eye and skin contact and do not breathe vapor and mist. Keep away from heat/sparks/open flames/hot surfaces – No smoking.

#### **For Non-Emergency Personnel**

**Protective equipment:** Use appropriate personal protection equipment (PPE).

**Emergency procedures:** Evacuate unnecessary personnel. Ventilate area. Eliminate ignition sources.

#### **For Emergency Personnel**

**Protective equipment:** Equip cleanup crew with proper protection.

### **Environmental Precautions**

Prevent entry to sewers and public waters.

### **Methods and Material for Containment and Cleaning Up**

**Methods for cleaning up:** For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal. Do not take up in combustible material such as: saw dust or cellulosic material. Use only non-sparking tools.

**Reference to Other Sections** See heading 8, Exposure Controls and Personal Protection.

## **7. HANDLING AND STORAGE**

### **Precautions for Safe Handling**

**Patients/Consumers:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

**Hygiene measures:** This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

### **Conditions for Safe Storage, Including Any Incompatibilities**

**Storage conditions:** Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight. Keep in fireproof place.

**Special rules on packaging:** Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

**Specific End Use(s)** Pharmaceutical. Refer to product insert for usage instructions and product information.

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **Control Parameters**

| <b>Ethyl alcohol (64-17-5)</b> |                         |                    |
|--------------------------------|-------------------------|--------------------|
| USA ACGIH                      | ACGIH STEL (ppm)        | 1000 ppm           |
| USA OSHA                       | OSHA PEL (TWA) (mg/m )  | 1900 mg/m          |
| USA OSHA                       | OSHA PEL (TWA) (ppm)    | 1000 ppm           |
| USA NIOSH                      | NIOSH REL (TWA) (mg/m ) | 1900 mg/m          |
| USA NIOSH                      | NIOSH REL (TWA) (ppm)   | 1000 ppm           |
| USA IDLH                       | US IDLH (ppm)           | 3300 ppm (10% LEL) |
| Alberta                        | OEL TWA (mg/m )         | 1880 mg/m          |
| Alberta                        | OEL TWA (ppm)           | 1000 ppm           |
| British Columbia               | OEL STEL (ppm)          | 1000 ppm           |
| Manitoba                       | OEL STEL (ppm)          | 1000 ppm           |
| New Brunswick                  | OEL TWA (mg/m )         | 1880 mg/m          |
| New Brunswick                  | OEL TWA (ppm)           | 1000 ppm           |
| New Foundland & Labrador       | OEL STEL (ppm)          | 1000 ppm           |
| Nova Scotia                    | OEL STEL (ppm)          | 1000 ppm           |
| Nunavut                        | OEL STEL (mg/m )        | 2355 mg/m          |

|                       |                  |           |
|-----------------------|------------------|-----------|
| Nunavut               | OEL STEL (ppm)   | 1250 ppm  |
| Nunavut               | OEL TWA (mg/m )  | 1884 mg/m |
| Nunavut               | OEL TWA (ppm)    | 1000 ppm  |
| Northwest Territories | OEL STEL (mg/m ) | 2355 mg/m |
| Northwest Territories | OEL STEL (ppm)   | 1250 ppm  |
| Northwest Territories | OEL TWA (mg/m )  | 1884 mg/m |
| Northwest Territories | OEL TWA (ppm)    | 1000 ppm  |
| Ontario               | OEL STEL (ppm)   | 1000 ppm  |
| Prince Edward Island  | OEL STEL (ppm)   | 1000 ppm  |
| Québec                | VEMP (mg/m )     | 1880 mg/m |
| Québec                | VEMP (ppm)       | 1000 ppm  |
| Saskatchewan          | OEL STEL (ppm)   | 1250 ppm  |
| Saskatchewan          | OEL TWA (ppm)    | 1000 ppm  |
| Yukon                 | OEL STEL (mg/m ) | 1900 mg/m |
| Yukon                 | OEL STEL (ppm)   | 1000 ppm  |
| Yukon                 | OEL TWA (mg/m )  | 1900 mg/m |
| Yukon                 | OEL TWA (ppm)    | 1000 ppm  |

### **Exposure Controls**

**Appropriate engineering controls:** Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

**Personal protective equipment:** Not generally required. The use of personal protective equipment may be necessary as conditions warrant. In case of splash hazard: safety glasses. Protective clothing. Gloves.

**Hand protection:** Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

**Eye protection:** In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

**Skin and body protection:** In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

**Respiratory protection:** When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

### **Information on Basic Physical and Chemical Properties**

|  |  |
|--|--|
| <b>Physical state</b>                                    | : Liquid   |
| <b>Appearance</b>  | : Clear, colorless to slightly yellow viscous solution |
| <b>Odor and Odor threshold</b>                           | : Not available  |
| <b>pH</b>  | : Not available  |
| <b>Relative evaporation rate (butyl acetate=1)</b>       | : Not available  |
| <b>Melting/Freezing point</b>                            | : Not available  |
| <b>Boiling point</b>                                     | : Not available  |
| <b>Flash point</b>                                       | : Not available  |
| <b>Auto-ignition temperature</b>                         | : Not available  |
| <b>Decomposition Temperature</b>                         | : Not available  |
| <b>Flammability (solid, gas)</b>                         | : Not available  |
| <b>Upper and Lower flammable limits</b>                  | : Not available  |
| <b>Vapor pressure</b>                                    | : Not available  |
| <b>Relative vapor density at 20 °C</b>                   | : Not available  |
| <b>Relative density/Specific gravity</b>                 | : Not available  |
| <b>Solubility</b>  | : Not available  |
| <b>Log Pow/Kow</b>                                       | : Not available  |
| <b>Viscosity</b>   | : Not available  |
| <b>Explosion data - sensitivity to mechanical impact</b> | : Not available  |
| <b>Explosion data - sensitivity to static discharge</b>  | : Not available  |

## **10. STABILITY AND REACTIVITY**

**Reactivity** Reacts violently with (strong) oxidizers: (increased) risk of fire/explosion.

**Chemical Stability** Stable under normal conditions.

**Possibility of Hazardous Reactions** Hazardous polymerization will not occur.

**Conditions to Avoid** Direct sunlight. Extremely high or low temperatures.  
**Incompatible Materials** Strong oxidizers. Strong bases. Strong acids.  
**Hazardous Decomposition Products** Carbon oxides (CO, CO<sub>2</sub>). Nitrogen compounds.

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects - Product

**Acute toxicity:** Not classified  
**LD50 and LC50 Data:** Not available  
**Skin Corrosion/Irritation:** Not classified  
**Serious Eye Damage/Irritation:** Causes serious eye irritation.  
**Respiratory or Skin Sensitization:** May cause an allergic skin reaction.  
**Germ Cell Mutagenicity:** Not classified  
**Teratogenicity:** Not available  
**Carcinogenicity:** Not classified  
**Specific Target Organ Toxicity (Repeated Exposure):** Not classified  
**Reproductive Toxicity:** Suspected of damaging fertility or the unborn child.  
**Specific Target Organ Toxicity (Single Exposure):** Not classified  
**Aspiration Hazard:** Not classified

### Information on Toxicological Effects - Ingredient(s)

#### **LD50 and LC50 Data:**

| <b>Ethyl alcohol (64-17-5)</b> |               |
|--------------------------------|---------------|
| LD50 oral rat                  | 10470 mg/kg   |
| LD50 dermal rat                | 20 ml/kg      |
| LC50 inhalation rat (mg/l)     | 124.7 mg/l/4h |

## 12. ECOLOGICAL INFORMATION

### Toxicity

| <b>Ethyl alcohol (64-17-5)</b> |  |
|--------------------------------|--|
| LC50 fish 1                    | 12.0 - 16.0 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |
| EC50 Daphnia 1                 | 9268 - 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)               |
| LC50 fish 2                    | > 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])       |

### Persistence and Degradability

| <b>Ethyl alcohol (64-17-5)</b> |                  |
|--------------------------------|------------------|
| Persistence and degradability  | Not established. |

### Bioaccumulative Potential

| <b>Ethyl alcohol (64-17-5)</b> |                  |
|--------------------------------|------------------|
| Log Pow                        | -0.32            |
| Bioaccumulative potential      | Not established. |

## 13. DISPOSAL CONSIDERATIONS

**Waste disposal recommendations:** Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.  
**Additional information:** Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

## 14. TRANSPORT INFORMATION

### **In Accordance With ICAO/IATA/DOT/TDG**

#### **UN Number**

UN-No.(DOT): 1170

DOT NA no.: UN1170

#### **UN Proper Shipping Name**

**DOT Proper Shipping Name** : Ethanol solutions

**Department of Transportation (DOT) Hazard Classes** : 3 - Class 3 - Flammable and combustible liquid 49 CFR 173.120

**Hazard labels (DOT)** : 3 - Flammable liquid



**Packing group (DOT)** : II - Medium Danger

**DOT Special Provisions (49 CFR 172.102)** : 24 - Alcoholic beverages containing more than 70 percent alcohol by volume must be transported as materials in Packing Group II. Alcoholic beverages containing more than 24 percent but not more than 70 percent alcohol by volume must be transported as materials in Packing Group III.  
 IB2 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized.  
 T4 - 2.65 178.274(d)(2) Normal..... 178.275(d)(3)  
 TP1 - The maximum degree of filling must not exceed the degree of filling determined by the following: Degree of filling =  $97 / (1 + a (tr - tf))$  Where: tr is the maximum mean bulk temperature during transport, and tf is the temperature in degrees celsius of the liquid during filling.

**DOT Packaging Exceptions (49 CFR 173.xxx)** : 4b;150

**DOT Packaging Non Bulk (49 CFR 173.xxx)** : 202

**DOT Packaging Bulk (49 CFR 173.xxx)** : 242

**Additional information**

**Emergency Response Guide (ERG) Number** : 127

**Transport by sea**

**DOT Vessel Stowage Location** : A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel.

**Air transport**

**DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27)** : 5 L

**DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75)** : 60 L

**15. REGULATORY INFORMATION**

**US Federal Regulations**

|  |   |
|--|---|
| <b>Semisynthetic Paclitaxel Injection, USP</b> |   |
| <b>SARA Section 311/312 Hazard Classes</b>     | Immediate (acute) health hazard<br>Delayed (chronic) health hazard<br>Fire hazard |

**Ethyl alcohol (64-17-5)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

**US State Regulations**

|  |  |
|--|--|
| <b>Paclitaxel (33069-62-4)</b>   |  |
| <b>U.S. - California - Proposition 65 - Developmental Toxicity</b>         | WARNING: This product contains chemicals known to the State of California to cause birth defects.              |
| <b>U.S. - California - Proposition 65 - Reproductive Toxicity - Female</b> | WARNING: This product contains chemicals known to the State of California to cause (Female) reproductive harm. |
| <b>U.S. - California - Proposition 65 - Reproductive Toxicity - Male</b>   | WARNING: This product contains chemicals known to the State of California to cause (Male) reproductive harm.   |

**Ethyl alcohol (64-17-5)**

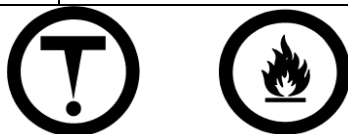
|  |   |
|--|---|
| <b>U.S. - California - Proposition 65 - Carcinogens List</b>       | WARNING: This product contains chemicals known to the State of California to cause cancer.        |
| <b>U.S. - California - Proposition 65 - Developmental Toxicity</b> | WARNING: This product contains chemicals known to the State of California to cause birth defects. |

**Ethyl alcohol (64-17-5)**

RTK - U.S. - Massachusetts - Right To Know List  
 RTK - U.S. - New Jersey - Right to Know Hazardous Substance List  
 RTK - U.S. - Pennsylvania - RTK (Right to Know) List

**Canadian Regulations**

|  |  |
|--|--|
| <b>Semisynthetic Paclitaxel Injection, USP</b> |  |
| <b>WHMIS Classification</b>                    | Class D Division 2 Subdivision A - Very toxic material causing other toxic effects<br>Class D Division 2 Subdivision B - Toxic material causing other toxic effects<br>Class B Division 2 - Flammable Liquid |



|   |  |
|---|--|
| <b>Ethyl alcohol (64-17-5)</b>  |  |
| Listed on the Canadian DSL (Domestic Substances List) inventory.<br>Listed on the Canadian Ingredient Disclosure List |  |
| WHMIS Classification  | Class B Division 2 - Flammable Liquid<br>Class D Division 2 Subdivision B - Toxic material causing other toxic effects |

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

|                              |
|------------------------------|
| <b>16. OTHER INFORMATION</b> |
|------------------------------|

- Revision date** : 07/23/2014
- Data sources** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
- Other information** : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

**GHS Full Text Phrases:**

|                   |  |
|-------------------|--|
| Aquatic Chronic 4 | Hazardous to the aquatic environment - Chronic Hazard Category 4 |
| Eye Dam. 1        | Serious eye damage/eye irritation Category 1                     |
| Eye Irrit. 2A     | Serious eye damage/eye irritation Category 2A                    |
| Flam. Liq. 2      | Flammable liquids Category 2                                     |
| Repr. 2           | Reproductive toxicity Category 2                                 |
| Skin Irrit. 2     | Skin corrosion/irritation Category 2                             |
| Skin Sens. 1      | Skin sensitization Category 1                                    |
| STOT SE 3         | Specific target organ toxicity (single exposure) Category 3      |
| H225              | Highly flammable liquid and vapor                                |
| H315              | Causes skin irritation   |
| H317              | May cause an allergic skin reaction                              |
| H318              | Causes serious eye damage  |
| H319              | Causes serious eye irritation                                    |
| H335              | May cause respiratory irritation                                 |
| H361              | Suspected of damaging fertility or the unborn child              |
| H413              | May cause long lasting harmful effects to aquatic life           |

**Party Responsible For The Preparation Of This Document:**

Mylan Global Environmental, Health, and Safety Department  
Phone Number: 304-599-2595

*This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.*

*To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.*

North America Mylan Pharmaceuticals