

## SAFETY DATA SHEET

**Product Name: Gemcitabine (gemcitabine hydrochloride) for Injection**

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

|   |  |  |
|---|--|--|
| <b>Manufacturer Names And Addresses</b> | Hospira, Inc.<br>275 North Field Drive<br>Lake Forest, Illinois 60045<br>USA   | Hospira Australia Pty Ltd<br>1 Lexia Place<br>Mulgrave VIC 3170<br>AUSTRALIA |
|   | ZHOPL Hospira Oncology Pvt. Ltd.<br>Plot No.3, Pharmez “Special Economic Zone”<br>Sarkhej- Bawla highway, (NH No 8A), Village: Matada, Tal Sanand,<br>Gujarat, India |  |
| <b>Emergency Telephone #'s</b>          | CHEMTREC: North America: 800-424-9300;<br>International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418  |  |
| <b>Hospira, Inc., Non-Emergency</b>     | 224 212-2000   |  |
| <b>Product Name</b>                     | Gemcitabine (gemcitabine hydrochloride) for Injection  |  |
| <b>Synonyms</b>                         | 2'-deoxy-2',2'-difluorocytidine monohydrochloride ( $\beta$ -isomer); Cytidine, 2'-deoxy-2',2'-difluoro-, monohydrochloride.   |  |

### 2. HAZARD(S) IDENTIFICATION

|                           |   |
|---------------------------|---|
| <b>Emergency Overview</b> | Gemcitabine (gemcitabine hydrochloride) for Injection is a powder containing gemcitabine hydrochloride, an analog of cytarabine that inhibits DNA synthesis and induces apoptosis (cell death). Clinically, gemcitabine hydrochloride is used to treat certain types of cancers. In the workplace, this material should be considered potentially irritating to the skin, eyes and respiratory tract, cytotoxic, neurotoxic, and a potential occupational reproductive hazard. Based on clinical use, possible target organs include the nervous system, blood, liver, and kidneys. |
|---------------------------|---|

#### U.S. OSHA GHS Classification

|                         |                                       |  |
|-------------------------|---------------------------------------|--|
| <b>Physical Hazards</b> | <b>Hazard Class</b><br>Not Classified | <b>Hazard Category</b><br>Not Classified |
|-------------------------|---------------------------------------|--|

|                       |   |  |
|-----------------------|---|--|
| <b>Health Hazards</b> | <b>Hazard Class</b><br>Acute Toxicity – Oral<br>Eye Damage / Irritation<br>Toxic to Reproduction<br>Germ Cell Mutagenicity<br>STOT – RE | <b>Hazard Category</b><br>4<br>2B<br>2<br>2<br>2 |
|-----------------------|---|--|

**Label Element(s)**  
**Pictogram**



**Signal Word**  
**Hazard Statement(s)**

Warning  
Harmful if swallowed  
Causes eye irritation  
Suspected of damaging fertility or the unborn child  
Suspected of causing genetic defects  
May cause damage to organs through prolonged or repeated exposure

**2. HAZARD(S) IDENTIFICATION: continued**

**Precautionary Statement(s)**

**Prevention**

Obtain special instructions before use  
 Do not handle until all safety precautions have been read and understood  
 Wear protective gloves/protective clothing/eye protection/face protection  
 Do not breathe vapor or spray  
 Wash hands thoroughly after handling  
 Do not eat, drink or smoke when using this product

**Response**

If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.  
 IF SWALLOWED: Call a poison center/doctor if you feel unwell.  
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Active Ingredient Name** Gemcitabine Hydrochloride  
**Chemical Formula** C<sub>9</sub>H<sub>11</sub>F<sub>2</sub>N<sub>3</sub>O<sub>4</sub> • HCl

| Component                 | Approximate Percent by Weight | CAS Number  | RTECS Number |
|---------------------------|-------------------------------|-------------|--------------|
| Gemcitabine Hydrochloride | 48.5                          | 122111-03-9 | HA3840000    |
| Sodium Acetate Trihydrate | 3                             | 6131-90-4   | AJ4580000    |

Non-hazardous ingredients include mannitol. Hazardous ingredients present at less than 1% include hydrochloric acid and/or sodium hydroxide which may be added to adjust the pH.

**4. FIRST AID MEASURES**

**Eye Contact** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**5. FIRE FIGHTING MEASURES**

**Flammability** None anticipated for this product. However, many organic powders will combust at elevated temperatures.

**Fire & Explosion Hazard** None anticipated for this product. Avoid the creation of dusty environments.

**Extinguishing Media** As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

**Special Fire Fighting Procedures** No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

**6. ACCIDENTAL RELEASE MEASURES**

**Spill Cleanup and Disposal** For spilled powder, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Absorb any liquid with an inert absorbent material (e.g. absorbent pad). Dispose of materials according to the applicable federal, state, or local regulations.

If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

**7. HANDLING AND STORAGE**

**Handling** Gemcitabine hydrochloride is a cytotoxic anti-neoplastic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic anti-neoplastic agents to minimize potential exposures. Several guidelines on handling cytotoxic anti-neoplastic agents have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate. Consult your hygienist or safety professional for your site requirements.

Avoid ingestion, inhalation, skin contact, and eye contact. If handling the powder, precautions may include the use of a containment cabinet during the weighing, reconstitution and/or solubilization of this antineoplastic agent. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials may be required when working with this material.

**Storage** No special storage is required for hazard control. However, employees should be trained on the proper storage procedures for anti-neoplastic agents. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions** No special precautions required for hazard control. Persons with known hypersensitivities to gemcitabine hydrochloride, women who are pregnant, or women who want to become pregnant, should consult a health and/or safety professional prior to handling open containers of this material.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Exposure Guidelines**

| Component                 | Exposure Limits           |                           |                           |                           |
|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
|                           | OSHA-PEL                  | ACGIH-TLV                 | AIHA WEEL                 | Hospira EEL               |
| Gemcitabine Hydrochloride | 8-hr TWA: Not Established | 8-hr TWA: Not Established | 8-hr TWA: Not Established | 8-hr TWA: Not Established |
| Sodium Acetate Trihydrate | 8-hr TWA: Not Established | 8-hr TWA: Not Established | 8-hr TWA: Not Established | 8-hr TWA: Not Established |

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
 AIHA WEEL: Workplace Environmental Exposure Level  
 EEL: Employee Exposure Limit.  
 TWA: 8-hour Time Weighted Average.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION: continued**

|                               |  |
|-------------------------------|--|
| <b>Respiratory Protection</b> | Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N99 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required. |
| <b>Skin Protection</b>        | When handling this material, disposable gloves should be worn at all times. Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to chemotherapy agents. Persons known to be allergic to latex rubber should select a non-latex glove. Gloves should be changed regularly, and removed immediately after known contamination. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.   |
| <b>Eye Protection</b>         | Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.   |
| <b>Engineering Controls</b>   | When handling, local exhaust ventilation is recommended to minimize employee exposure. The use of an enclosure, such as an approved ventilated cabinet designed to minimize airborne exposures, is also recommended.   |

**9. PHYSICAL/CHEMICAL PROPERTIES**

|   |  |
|---|--|
| <b>Appearance/Physical State</b>                    | White to off-white powder in a vial. Reconstituted Gemcitabine for Injection, USP is a clear and colorless to light straw-colored solution |
| <b>Odor</b>   | Odorless   |
| <b>Odor Threshold</b>                               | NA   |
| <b>pH</b>   | After reconstitution with 0.9% Sodium Chloride Injection, the pH of the resulting solution lies in the range of 2.7 to 3.3                 |
| <b>Melting point/Freezing Point</b>                 | NA   |
| <b>Initial Boiling Point/Boiling Point Range</b>    | NA   |
| <b>Flash Point</b>                                  | NA   |
| <b>Evaporation Rate</b>                             | NA   |
| <b>Flammability (solid, gas)</b>                    | NA   |
| <b>Upper/Lower Flammability or Explosive Limits</b> | NA   |
| <b>Vapor Pressure</b>                               | NA   |
| <b>Vapor Density (Air =1)</b>                       | NA   |
| <b>Relative Density</b>                             | NA   |
| <b>Solubility</b>                                   | Soluble in water, slightly soluble in methanol, and practically insoluble in ethanol and polar organic solvents                            |
| <b>Partition Coefficient: n-octanol/water</b>       | NA   |
| <b>Auto-ignition Temperature</b>                    | NA   |
| <b>Decomposition Temperature</b>                    | NA   |
| <b>Viscosity</b>                                    | NA   |

**10. STABILITY AND REACTIVITY**

|   |   |
|---|---|
| <b>Reactivity</b>                       | Not determined.   |
| <b>Chemical Stability</b>               | Stable under standard use and storage conditions.   |
| <b>Hazardous Reactions</b>              | Not determined  |
| <b>Conditions to Avoid</b>              | Not determined  |
| <b>Incompatibilities</b>                | Not determined  |
| <b>Hazardous Decomposition Products</b> | Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), hydrogen chloride and hydrogen fluoride. |
| <b>Hazardous Polymerization</b>         | Not anticipated to occur with this product.   |

**11. TOXICOLOGICAL INFORMATION**

**Acute Toxicity** - Not determined for the product formulation. Information for ingredients is as follows:

| <b>Ingredient(s)</b>       | <b>Percent</b> | <b>Test Type</b> | <b>Route of Administration</b> | <b>Value</b> | <b>Units</b>   | <b>Species</b> |
|----------------------------|----------------|------------------|--------------------------------|--------------|----------------|----------------|
| *Gemcitabine Hydrochloride | 100            | LD50             | Oral                           | >500         | mg/kg          | Rat            |
| *Gemcitabine Hydrochloride | 100            | LDLo             | Oral                           | 333          | mg/kg          | Mouse          |
| Gemcitabine Hydrochloride  | 100            | LD50             | Intravenous                    | 236          | mg/kg          | Rat            |
| Gemcitabine Hydrochloride  | 100            | LD50             | Intravenous                    | 500          | mg/kg          | Mouse          |
| *Gemcitabine Hydrochloride | 51-53          | LD50             | Dermal                         | >1000        | mg/kg          | Rabbit         |
| Sodium Acetate             | 100            | LD50             | Oral                           | 3530<br>6891 | mg/kg<br>mg/kg | Rat<br>Mouse   |
| Sodium Acetate             | 100            | LD50             | Dermal                         | > 10,000     | mg/kg          | Rabbit         |

LD 50: Dosage that produces 50% mortality.

\*Eli Lilly and Company MSDS

|  |  |
|--|--|
| <b>Occupational Exposure Potential</b>     | Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust or liquid aerosol generation and skin contact. There are scientific studies that suggest that personnel (e.g. nurses, pharmacists, etc.) who prepare and administer parenteral antineoplastics (e.g. in hospitals) may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these materials if workplace exposures are not properly controlled. The actual risk in the workplace is not known. |
| <b>Signs and Symptoms</b>                  | None anticipated from normal handling of this product. In clinical use, adverse effects have included bone marrow suppression (leukopenia, neutropenia, thrombocytopenia, and anemia), nausea, vomiting, diarrhea or constipation, pain, fever, rash, alopecia, stomatitis, dyspnea, hemorrhage, neurotoxicity (mild paresthesias), elevated liver enzymes, and adverse renal effects (proteinuria and hematuria).   |
| <b>Aspiration Hazard</b>                   | None anticipated from normal handling of this product.   |
| <b>Dermal Irritation/Corrosion</b>         | None anticipated from normal use of this product. However, inadvertent skin contact with this product may produce skin irritation with redness.  |
| <b>Ocular Irritation/ Corrosion</b>        | None anticipated from normal use of this product. However, inadvertent eye contact with this produce may produce eye irritation with tearing, redness and discomfort.  |
| <b>Dermal or Respiratory Sensitization</b> | None anticipated from normal handling of this product. Gemcitabine hydrochloride was negative in a sensitization assay in guinea pigs. Hypersensitivity reactions have been reported infrequently during the clinical use of this product.   |

**11. TOXICOLOGICAL INFORMATION: continued**

|   |   |
|---|---|
| <b>Reproductive Effects</b>                             | None anticipated from normal handling of this product. Intraperitoneal administration of gemcitabine to male mice at a dosage of 0.5 mg/kg/day produced moderate to severe hypospermatogenesis, decreased fertility, and decreased implantations. In female mice, fertility was not affected but maternal toxicities were noted at intravenous dosages of 1.5 mg/kg/day, and fetotoxicity or embryoletality was observed at an intravenous dosage of 0.25 mg/kg/day. Gemcitabine is embryotoxic, producing fetal malformations (cleft palate, incomplete ossification) at a dosage of 1.5 mg/kg/day in mice. Gemcitabine is fetotoxic causing fetal malformations (fused pulmonary artery, absence of gall bladder) at a dosage of 0.1 mg/kg/day in rabbits. Embryotoxicity is characterized by decreased fetal viability, reduced live litter sizes, and developmental delays. |
| <b>Mutagenicity</b>                                     | Gemcitabine induced forward mutations <i>in vitro</i> in a mouse lymphoma (L5178Y) assay and was clastogenic in an <i>in vivo</i> mouse micronucleus assay. Gemcitabine was negative when tested using the Ames, <i>in vivo</i> sister chromatid exchange, and <i>in vitro</i> chromosomal aberration assays; it did not cause unscheduled DNA synthesis <i>in vitro</i> .  |
| <b>Carcinogenicity</b>                                  | Long-term animal studies to evaluate the carcinogenic potential of gemcitabine have not been conducted.   |
| <b>Carcinogen Lists</b>                                 | <b>IARC:</b> Not listed <b>NTP:</b> Not listed <b>OSHA:</b> Not listed  |
| <b>Specific Target Organ Toxicity – Single Exposure</b> | NA  |
| <b>Specific Target Organ Toxicity – Repeat Exposure</b> | Based on clinical use, possible target organs include the nervous system, blood, liver, and kidneys.  |

**12. ECOLOGICAL INFORMATION**

|                                       |   |
|---------------------------------------|---|
| <b>*Aquatic Toxicity</b>              | Not determined for product. Information for gemcitabine hydrochloride* is as follows:<br><br>LC50(96 hr) > 1043 mg/L in rainbow trout<br>LC50(96 hr) > 1014 mg/L in fathead minnow<br>EC50(4h hr) > 999 mg/L in Daphnia magna<br>EC50 = 5.4 mg/L in Green algae (S. capricornutum)<br><br>MIC* > 1000 mg/L in Chaetomium globosum (fungus)<br>MIC > 1000 mg/L in Aspergillus flavus (mold)<br>MIC > 1000 mg/L in Comamonas acidovorans (soil bacteria)<br>MIC > 1000 mg/L in Azotobacter chroococcum (a nitrogen-fixing bacteria)<br>MIC = 800 mg/L in Nostoc sp. (a blue-green algae)<br><br>* MIC = Minimum Inhibitor Concentration |
| <b>*Persistence/ Biodegradability</b> | Not determined for product. Information for gemcitabine hydrochloride* is as follows:<br><br>Based on reported results, not considered Ready Biodegradable.<br>Based on reported results, hydrolysis not considered a pathway of degradation in the environment.  |
| <b>Bioaccumulation</b>                | Not determined for product.   |
| <b>Mobility in Soil</b>               | Not determined for product.   |

\*Eli Lilly and Company MSDS

Notes:

1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EC50: Concentration in water that produces 50% inhibition of growth in algae.

### 13. DISPOSAL CONSIDERATIONS

|  |   |
|--|---|
| <b>Waste Disposal</b>                  | All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements. |
| <b>Container Handling and Disposal</b> | Dispose of container and unused contents in accordance with federal, state and local regulations.   |

### 14. TRANSPORTATION INFORMATION

|                             |               |
|-----------------------------|---------------|
| <b>ADR/ADG/ DOT STATUS</b>  | Not regulated |
| <b>Proper Shipping Name</b> | NA            |
| <b>Hazard Class</b>         | NA            |
| <b>UN Number</b>            | NA            |
| <b>Packing Group</b>        | NA            |
| <b>Reportable Quantity</b>  | NA            |

|                             |               |
|-----------------------------|---------------|
| <b>ICAO/IATA STATUS</b>     | Not regulated |
| <b>Proper Shipping Name</b> | NA            |
| <b>Hazard Class</b>         | NA            |
| <b>UN Number</b>            | NA            |
| <b>Packing Group</b>        | NA            |
| <b>Reportable Quantity</b>  | NA            |

|                             |               |
|-----------------------------|---------------|
| <b>IMDG STATUS</b>          | Not regulated |
| <b>Proper Shipping Name</b> | NA            |
| <b>Hazard Class</b>         | NA            |
| <b>UN Number</b>            | NA            |
| <b>Packing Group</b>        | NA            |
| <b>Reportable Quantity</b>  | NA            |

Notes: DOT - US Department of Transportation Regulations

### 15. REGULATORY INFORMATION

|                            |            |
|----------------------------|------------|
| <b>US TSCA Status</b>      | Exempt.    |
| <b>US CERCLA Status</b>    | Not listed |
| <b>US SARA 302 Status</b>  | Not listed |
| <b>US SARA 313 Status</b>  | Not listed |
| <b>US RCRA Status</b>      | Not listed |
| <b>US PROP 65 (Calif.)</b> | Not listed |

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65



**15. REGULATORY INFORMATION: continued**

**GHS/CLP Classification\***

\*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

| Hazard Class | Hazard Category | Pictogram | Signal Word | Hazard Statement |
|--------------|-----------------|-----------|-------------|------------------|
| NA           | NA              | NA        | NA          | NA               |

**Prevention**

Obtain special instructions before use  
 Do not handle until all safety precautions have been read and understood  
 Wear protective gloves/protective clothing/eye protection/face protection  
 Do not breathe vapor or spray  
 Wash hands thoroughly after handling  
 Do not eat, drink or smoke when using this product

**Response**

If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.  
 IF SWALLOWED: Call a poison center/doctor if you feel unwell.  
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

**EU Classification\***

\*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

**Classification(s)**  
**Symbol**  
**Indication of Danger**  
**Risk Phrases**  
**Safety Phrases**

NA  
 NA  
 NA  
 NA  
 S23: Do not breathe vapor/spray  
 S24: Avoid contact with the skin  
 S25: Avoid contact with eyes  
 S37/39 Wear suitable gloves and eye/face protection.

**16. OTHER INFORMATION**

Notes:

|                  |   |
|------------------|---|
| ACGIH TLV        | American Conference of Governmental Industrial Hygienists – Threshold Limit Value |
| CAS              | Chemical Abstracts Service Number   |
| CERCLA           | US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act |
| DOT              | US Department of Transportation Regulations                                       |
| EEL              | Employee Exposure Limit   |
| IATA             | International Air Transport Association   |
| LD <sub>50</sub> | Dosage producing 50% mortality  |
| NA               | Not applicable/Not available  |
| NE               | Not established   |
| NIOSH            | National Institute for Occupational Safety and Health                             |
| OSHA PEL         | US Occupational Safety and Health Administration – Permissible Exposure Limit     |
| Prop 65          | California Proposition 65   |
| RCRA             | US EPA, Resource Conservation and Recovery Act                                    |
| RTECS            | Registry of Toxic Effects of Chemical Substances                                  |
| SARA             | Superfund Amendments and Reauthorization Act                                      |
| STEL             | 15-minute Short Term Exposure Limit   |
| STOT - SE        | Specific Target Organ Toxicity – Single Exposure                                  |
| STOT - RE        | Specific Target Organ Toxicity – Repeated Exposure                                |
| TSCA             | Toxic Substance Control Act   |
| TWA              | 8-hour Time Weighted Average  |



**16. OTHER INFORMATION:** continued

MSDS Coordinator: Hospira GEHS  
Date Prepared: October 18, 2012  
Date Revised: June 02, 2014

**Disclaimer:**

The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.