SECTION 1: IDENTIFICATION

Product Identifier
Product Name: Cyanocobalamin Injection USP
Other Name: Vitamin $B_12$ Injection, Cyanocobalamin Solution for Injection 1000 mcg/mL
Chemical Family: Mixture

Product Use: Pharmaceutical (Solution for Injection)

Supplier: Teligent Canada Inc.
5995 Avebury Road, Suite 804
Mississauga, Ontario L5R 3P9
1-800-656-0793

Manufacturer: Teligent OÜ
Akadeemia tee 21/5, Tallinn, Estonia

Emergency Phone Number:
Chemical Emergency Response Unit (Canada): 1-613-946-5690
Poison Control Center (US): 1-800-222-1222

SECTION 2: HAZARD IDENTIFICATION

This pharmaceutical product is for human use under prescribed dosage form. Under normal handling and use, and in a manner consistent with the labeled instructions, this product is not chemically hazardous.

Classification of the Substance or Mixture
GHS – Classification: Not classified as hazardous substance or mixture.

Label Elements
Signal Word: Not a hazardous substance or mixture
Hazard Statements: Not classified in accordance with international standards for workplace safety.

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

Composition of 1 mL Dosage (Without Preservative)

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS Number</th>
<th>Quantity</th>
<th>Acute toxicity, LD50 (Oral, Rat)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyanocobalamin</td>
<td>68-19-9</td>
<td>1.0 mg/mL</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>7647-14-5</td>
<td>7.5 mg/mL</td>
<td>3550 mg/kg</td>
</tr>
<tr>
<td>Sodium Acetate Trihydrate</td>
<td>6131-90-4</td>
<td>2.07 mg/mL</td>
<td>3530 mg/kg</td>
</tr>
<tr>
<td>Glacial Acetic Acid</td>
<td>64-19-7</td>
<td>For pH adjustment</td>
<td>3310 mg/kg</td>
</tr>
<tr>
<td>Purified Water for Injection</td>
<td>7732-18-5</td>
<td>-</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
Composition of 10 mL Dosage (With Preservative)

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS Number</th>
<th>Quantity</th>
<th>Acute toxicity, LD50 (Oral, Rat)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyanocobalamin</td>
<td>68-19-9</td>
<td>1.0 mg/mL</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>7647-14-5</td>
<td>9.0 mg/mL</td>
<td>3550 mg/kg</td>
</tr>
<tr>
<td>Sodium Acetate Trihydrate</td>
<td>6131-90-4</td>
<td>0.5 mg/mL</td>
<td>3530 mg/kg</td>
</tr>
<tr>
<td>Glacial Acetic Acid</td>
<td>64-19-7</td>
<td>0.1 mg/mL</td>
<td>3310 mg/kg</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>15.0 mg/mL</td>
<td>1620 mg/kg</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>1310-73-2</td>
<td>For pH adjustment</td>
<td>No data available</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>For pH adjustment</td>
<td>No data available</td>
</tr>
<tr>
<td>Purified Water for Injection</td>
<td>7732-18-5</td>
<td>-</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

SECTION 4: FIRST AID MEASURES

After Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

After Skin Contact: Remove clothing and wash affected skin with plenty of soap and water. If irritation occurs or persists, get medical attention.

After Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

After Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water.

SECTION 5: FIRE FIGHTING MEASURES

Conditions of Flammability: Not Flammable or Combustible

Fire Fighting Instructions: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Explosion Hazards: Not applicable.

Extinguishing Media: Use extinguishing media appropriate to surrounding fire conditions, such as water spray, dry chemical, alcohol-resistant foam, carbon dioxide.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
**Additional Consideration for Large Spills:**
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

**SECTION 7: HANDLING AND STORAGE**

**Precautions for Safe Handling**
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use with adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided.

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store at room temperature between 15 and 30°C. Protect from light. Protect from freezing. For details information refer to the product packaging.

**Incompatible Materials:** Avoid exposure to light. Vial stopper contains no dry natural rubber.

**SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION**

**Control parameters**
No data available

**Personal Protection Equipment**
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Eye Protection:** Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

**Skin Protection:** Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.

**Hand Protection:** Protective gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove’s outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

**Respiratory Protection:** Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, wear an appropriate respirator with a protection factor sufficient to control exposures.
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Colour: Red
Odour: Not applicable
Odour threshold: No data available
Molecular Formula: Mixture
Molecular Weight: Mixture
Specific Gravity: 1.0045 g/mL
pH: 4.5 – 7.0
Boiling Point: Mixture
Freezing Point: Mixture
Solubility in Water: Soluble
Flash Point: No data available
Vapor Density: No data available
Evaporation Rate: No data available
Partition Coefficient: No data available
Flammability: No data available
Auto-ignition Temperature: No data available
Decomposition Temperature: No data available
Viscosity: No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use
Possibility of Hazardous Reactions: No data available
Conditions to Avoid: Direct sunlight, conditions that might generate heat, and sources of ignition. Protect from freezing.

Incompatibility: No data available
Hazardous Decomposition Products: Hazardous decomposition products may formed under fire conditions:- Carbon oxides, Nitrogen oxides (NOx), Oxides of phosphorus, Cobalt/cobalt oxides.

SECTION 11: TOXIOLOGICAL INFORMATION

Acute toxicity (Species, Root, Endpoint, Dose)

Cyanocobalamin
Rat Oral LD50 > 5000 mg/kg
Mouse Intravenous LD50 2000 mg/kg
Sodium Chloride
- Rat, Oral, LD50: 3550 mg/kg
- Rabbit, Dermal, LD50: >10000 mg/kg
- Rat, Inhalation, LC50 – 1hr: >42000 mg/m³

Acetic Acid
- Rat, Oral, LD50: 3310 mg/kg
- Rat, Inhalation, LC50 – 4hr: 11.4 mg/L
- Rabbit, Dermal, LD50: 1112 mg/kg

Benzyl Alcohol
- Rat, Oral, LD50: 1620 mg/kg

Sodium Acetate
- Rat, Oral, LD50: 3530 mg/kg
- Rabbit, Dermal, LD50: >10000 mg/kg
- Rat, Inhalation, LC50 – 1hr: >30000 mg/m³

Other information on acute toxicity
No data available

Skin corrosion/irritation
No data available

Serious eye damage/eye irritation
No data available

Respiratory or skin sensitization
No data available

Germ cell mutagenicity
No data available

Carcinogenicity
None of the components of this formulation are listed as a carcinogen by IARC, ACGIH or OSHA.

Reproductive toxicity
No data available

Teratogenicity
No data available

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Cyanocobalamin
No data available

Sodium Chloride
Toxicity to fish
LC50 – Lepomis macrochirus (Bluegill) - 5840 mg/l – 96 hr
Toxicity to daphnia and other aquatic invertebrates
LC50 – Daphnia magna (Water flea) - 1661 mg/l – 48 hr

**Acetic Acid**
Toxicity to fish
LC50 – Oncorhynchus mykiss (Rainbow Trout) - >1000 mg/l – 96 hr (OECD)

Toxicity to daphnia and other aquatic invertebrates
EC50 – Daphnia magna (Water flea) - > 300.82 mg/l – 48 hr  (OECD)

**Benzyl Alcohol**
Toxicity to fish
LC50 – Pimephales promelas (Fathead Minnow) - 460 mg/l – 96 hr (US-EPA)

Toxicity to daphnia and other aquatic invertebrates
EC50 – Daphnia magna (Water flea) - 230 mg/l – 48 hr  (OECD)

**Sodium Acetate**
Toxicity to fish
LC50 – Pimephales promelas (Fathead Minnow) - 13330 mg/l – 120 hr
LC50 – Lepomis macrochirus (Bluegill) - 5000 mg/l – 24 hr

Toxicity to daphnia and other aquatic invertebrates
EC50 – Daphnia magna (Water flea) - >1000 mg/l – 48 hr

**Persistence and degradability**
No data available

**Bioaccumulative potential**
No data available

**Mobility in soil**
No data available

**Other adverse effects**
No data available

**SECTION 13: DISPOSAL CONSIDERATIONS**

**Waste Disposal:** Dispose of in accordance with all applicable federal, state and local regulations. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases.
Packaging: Dispose of in accordance with all applicable federal, state and local regulations. Handle packaging in the same way as the product itself. If not officially specified differently, packaging may be treated like household waste or recycled.

SECTION 14: TRANSPORTATION INFORMATION

Not regulated for transport under USDOT (transportation by land), IATA (transportation by air) or IMDG (transportation by sea) regulations.

SECTION 15: REGULATORY INFORMATION

The product described in this SDS is regulated under the Federal Food, Drug and Cosmetics Act and is safe to use as per directions on container, box or accompanying literature (where applicable).

SECTION 16: OTHER INFORMATION

The information contained in this Safety Data Sheet has been compiled from information believed to be accurate. While we believe that the data presented here is factual, Teligent Canada Inc. and its affiliates make no warranty or representation, nor assumes any responsibility in conjunction with the use of this information.

Latest Revision: January 09, 2019