

# MATERIAL SAFETY DATA SHEET

Version No: MSDS/Bus-AUS/DP-002

Effective Date: 14<sup>th</sup> October 2024

## BUSULFAN CONCENTRATED INJECTION 60 MG/10 ML

### SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Busulfan Accord Concentrated Injection  
60 mg/10 mL

| Sponsor   | Manufacturer  |
|---|---|
| Accord Healthcare Pty Ltd<br>Level 24, 570 Bourke Street,<br>Melbourne, VIC, 3000,<br>Australia<br><br>Telephone: 1800 222 673<br>(hours 8:30am – 4:30pm) | Intas Pharmaceuticals Ltd.<br>Plot No. 457, 458<br>Village-Matoda,<br>Bavla Road, Ta. Sanand,<br>Dist. Ahmedabad-382 210,<br>Gujarat, India |

### SECTION 2 – HAZARD(S) IDENTIFICATION

#### Classification of the Substance or Mixture:

#### GHS – Classification:

Serious Eye Damage/Eye Irritation      Category 2A  
Germ Cell Mutagenicity                      : Category 1B  
Reproductive Toxicity                        : Category 1B  
Carcinogenicity                                Category 1B



#### Label Elements:

**Signal Word:** Danger

#### Hazard Statements:

H319            - Causes serious eye irritation  
H340            - May cause genetic defects  
H350            - May cause cancer  
H360FD        - May damage fertility. May damage the unborn child

#### Precautionary Statements:

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- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P264 - Wash hands thoroughly after handling
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P337 + P313 - If eye irritation persists: Get medical advice/attention
- P405 - Store locked up

**Other Hazards:** An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**Note:** This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

**Active:** Busulfan.

**Inactive:** Dimethylacetamide, Macrogol 400.

| Ingredient             | CAS Number | EU EINECS/ELINCS List | GHS Classification   | %       |
|------------------------|------------|-----------------------|--|---------|
| Busulfan               | 55-98-1    | 200-250-2             | Repr. 1B (H360FD)<br>Carc. 1B (H350)<br>Muta. 1B (H340)                                | < 1     |
| N,N- Dimethylacetamide | 127-19-5   | 204-826-4             | Repr. 1B (H360D)<br>Acute Tox. 4 (H312)<br>Acute Tox. 4 (H332)<br>Eye Irrit. 2A (H319) | 30 - 35 |
| Polyethylene glycol    | 25322-68-3 | Not Listed            | Not Listed   | *       |

**Additional Information:**

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

**For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16**

## SECTION 4 - FIRST AID MEASURES

**Description of Necessary First Aid Measures:**

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Symptoms and Effects of Exposure:** No data available.

**Medical Conditions Aggravated by Exposure:** None known.

**Medical Attention and Special Treatment:** None.

## SECTION 5 - FIRE FIGHTING MEASURES

**Suitable Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture:** Formation of toxic gases is possible during heating or fire.

**Special Protective Equipment and Precautions for Fire-Fighters:** During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Fine particles (such as mists) may fuel fires/explosions.

## 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:** 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. When handling, use appropriate personal protective equipment (see Section 8). Wash hands

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and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Conditions for Safe Storage, Including any Incompatibilities:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical product used as Antineoplastic.

## SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters – Exposure Standards, Biological Monitoring:

#### N,N- Dimethylacetamide:

|                                      |  |
|--------------------------------------|--|
| ACGIH Threshold Limit Value (TWA)    | : 10 ppm   |
| ACGIH - Biological Exposure Limit    | : 30 mg/g creatinine   |
| ACGIH - Skin Absorption Designation  | : Skin - potential significant contribution to overall exposure by the cutaneous route |
| Australia TWA                        | : 10 ppm<br>36 mg/m <sup>3</sup>   |
| Austria OEL - MAKs                   | : 10 ppm<br>36 mg/m <sup>3</sup>   |
| Belgium OEL - TWA                    | : 10 ppm<br>36 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                   | : 10 ppm<br>36 mg/m <sup>3</sup>   |
| Cyprus OEL - TWA                     | : 10 ppm<br>36 mg/m <sup>3</sup>   |
| Czech Republic OEL - TWA             | : 30 mg/m <sup>3</sup>   |
| Denmark OEL - TWA                    | : 10 ppm<br>36 mg/m <sup>3</sup>   |
| Estonia OEL - TWA                    | : 10 ppm<br>36 mg/m <sup>3</sup>   |
| Finland OEL - TWA                    | : 10 ppm<br>36 mg/m <sup>3</sup>   |
| France OEL - TWA                     | : 2 ppm<br>7.2 mg/m <sup>3</sup>   |
| Germany - TRGS 900 - TWAs            | : 10 ppm<br>36 mg/m <sup>3</sup>   |
| Germany (DFG) - MAK                  | : 10 ppm<br>36 mg/m <sup>3</sup>   |
| Germany - Biological Exposure Limit: | : 30 mg/g  |
| Greece OEL - TWA                     | : 10 ppm<br>36 mg/m <sup>3</sup>   |

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|   |   |   |
|---|---|---|
| <b>Hungary OEL - TWA</b>                    | : | 36 mg/m <sup>3</sup>                                    |
| <b>Ireland OEL - TWAs</b>                   | : | 10 ppm<br>36 mg/m <sup>3</sup>                          |
| <b>Italy OEL - TWA</b>                      | : | 10 ppm<br>36 mg/m <sup>3</sup>                          |
| <b>Latvia OEL - TWA</b>                     | : | 10 ppm<br>36 mg/m <sup>3</sup>                          |
| <b>Lithuania OEL - TWA</b>                  | : | 10 ppm<br>36 mg/m <sup>3</sup>                          |
| <b>Luxembourg OEL - TWA</b>                 | : | 10 ppm<br>36 mg/m <sup>3</sup>                          |
| <b>Malta OEL - TWA</b>                      | : | 10 ppm<br>36 mg/m <sup>3</sup>                          |
| <b>Netherlands OEL - TWA</b>                | : | 36 mg/m <sup>3</sup>                                    |
| <b>OSHA - Final PELs - TWAs:</b>            | : | 10 ppm<br>35 mg/m <sup>3</sup>                          |
| <b>OSHA - Final PELs - Skin Notations:</b>  | : | prevent or reduce skin absorption                       |
| <b>Poland OEL - TWA</b>                     | : | 35 mg/m <sup>3</sup>                                    |
| <b>Portugal OEL - TWA</b>                   | : | 10 ppm<br>36 mg/m <sup>3</sup>                          |
| <b>Romania OEL - TWA</b>                    | : | 10 ppm<br>36 mg/m <sup>3</sup>                          |
| <b>Romania - Biological Exposure Limit:</b> | : | 30 µg/g Creatinine                                      |
| <b>Russia OEL - TWA</b>                     | : | 1 mg/m <sup>3</sup>                                     |
| <b>Slovakia OEL - TWA</b>                   | : | 10 ppm<br>36 mg/m <sup>3</sup>                          |
| <b>Slovenia OEL - TWA</b>                   | : | 10 ppm<br>36 mg/m <sup>3</sup>                          |
| <b>Spain OEL - TWA</b>                      | : | 10 ppm<br>36 mg/m <sup>3</sup>                          |
| <b>Spain - Biological Exposure Limit:</b>   | : | 30 mg/g Creatinine                                      |
| <b>Sweden OEL - TWAs</b>                    | : | 10 ppm<br>35 mg/m <sup>3</sup>                          |
| <b>Switzerland OEL -TWAs</b>                | : | 10 ppm<br>35 mg/m <sup>3</sup>                          |
| <b>UK - Biological Exposure Limit:</b>      | : | 100 mmol/mol creatinine                                 |
| <b>Polyethylene glycol:</b>                 |   |   |
| <b>Austria OEL - MAKs</b>                   | : | 1000 mg/m <sup>3</sup>                                  |
| <b>Germany - TRGS 900 - TWAs</b>            | : | 1000 mg/m <sup>3</sup>                                  |
| <b>Germany (DFG) - MAK</b>                  | : | 1000 mg/m <sup>3</sup> average molecular weight 200-600 |
| <b>Slovakia OEL - TWA</b>                   | : | 1000 mg/m <sup>3</sup>                                  |
| <b>Slovenia OEL - TWA</b>                   | : | 1000 mg/m <sup>3</sup>                                  |
| <b>Switzerland OEL -TWAs</b>                | : | 1000 mg/m <sup>3</sup>                                  |

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**Appropriate 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.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

|   |                     |
|---|---------------------|
| <b>Appearance</b>                                     | : Solution          |
| <b>Colour</b>   | : Clear, colourless |
| <b>Odour</b>  | : No data available |
| <b>Odour Threshold</b>                                | : No data available |
| <b>Solvent Solubility</b>                             | : No data available |
| <b>Water Solubility</b>                               | : No data available |
| <b>pH</b>   | : No data available |
| <b>Melting/Freezing Point (°C)</b>                    | : No data available |
| <b>Boiling Point and boiling range (°C)</b>           | : No data available |
| <b>Partition Coefficient (<i>n</i>-octanol/water)</b> |                     |
| <b>N,N- Dimethylacetamide</b>                         | : No data available |
| <b>Polyethylene glycol</b>                            | : No data available |
| <b>Busulfan</b>                                       | : No data available |
| <b>Decomposition Temperature (°C)</b>                 | : No data available |
| <b>Evaporation Rate (Gram/s)</b>                      | : No data available |
| <b>Vapour Pressure (kPa)</b>                          | : No data available |
| <b>Vapour Density (g/ml)</b>                          | : No data available |
| <b>Relative Density</b>                               | : No data available |

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|   |                     |
|---|---------------------|
| Viscosity   | : No data available |
| Auto-ignition Temperature (Solid) (°C)                      | : No data available |
| Flammability (Solids)                                       | : No data available |
| Flash Point (Liquid) (°C)                                   | : No data available |
| Upper Flammability or Explosive Limits (Liquid) (% by Vol.) | : No data available |
| Lower Flammability or Explosive Limits (Liquid) (% by Vol.) | : No data available |

## SECTION 10 - STABILITY AND REACTIVITY

**Reactivity:** No data available.

**Chemical Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** Fine particles (such as mists) may fuel fires/explosions.

**Incompatible Materials and Possible Hazardous Reactions:** As a precautionary measure, keep away from strong oxidizers.

**Hazardous Decomposition Products:** No data available.

## SECTION 11 – TOXICOLOGICAL INFORMATION

The information included in this section describes the potential hazards of the active ingredient.

**Information on Toxicological Effects:** Common adverse effects include seizure myelosuppression, cardiac tamponade, pulmonary dysfunction, fever, headache, loss of strength/exhaustion (prostration), increased heart rate (tachycardia), increase in blood pressure (hypertension), nausea, inflammation of the mouth (stomatitis), vomiting, loss of appetite (anorexia), insomnia, diarrhea, and anxiety. May cause adverse effects on the developing fetus.

**Acute Toxicity:**

**N,N- Dimethylacetamide:**

| Species | Route      | End Point | Dose       |
|---------|------------|-----------|------------|
| Rabbit  | Dermal     | LD 50     | 2240 mg/kg |
| Rat     | Inhalation | LC50 1H   | 8.81 mg/L  |

**Irritation / Sensitization:**

**Polyethylene glycol:**

| Study Type      | Species | Severity |
|-----------------|---------|----------|
| Eye Irritation  | Rabbit  | Mild     |
| Skin Irritation | Rabbit  | Mild     |

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## Reproduction & Development Toxicity:

### Busulfan:

| Duration                   | Species | Route | Dose         | End Point | Effect(s)  |
|----------------------------|---------|-------|--------------|-----------|--|
| Embryo / Fetal Development | Rat     | Oral  | 48 mg/kg/day | LOAEL     | Teratogenic, Early embryonic development               |
| Reproductive & Fertility   | Rat     | Oral  | 49 mg/kg/day | LOAEL     | Fertility  |
| Embryo / Fetal Development | Rabbit  | Oral  | 32 mg/kg/day | LOAEL     | Teratogenic, Fetotoxicity, Early embryonic development |
| Embryo / Fetal Development | Mouse   | Oral  | 40 mg/kg/day | LOAEL     | Teratogenic, Fetotoxicity, Early embryonic development |

## Genetic Toxicity:

### Busulfan:

| Study Type                           | Cell Type/Organism | Result   |
|--------------------------------------|--------------------|----------|
| <i>In Vivo</i> Chromosome Aberration | Rat                | Positive |
| Bacterial Mutagenicity (Ames)        | <i>Salmonella</i>  | Positive |
| <i>In Vivo</i> Direct DNA Damage     | Rat Hepatocyte     | Positive |
| Sister Chromatid Exchange            | Human Lymphocytes  | Positive |
| Unscheduled DNA Synthesis            | Mouse              | Positive |

**Carcinogen Status:** See below.

### Busulfan:

LARC: Group 1 (Carcinogenic to Humans)

NTP: Known Human Carcinogen

## SECTION 12 – ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

**Ecotoxicity:** No data available.

**Persistence and Degradability:** No data available.

**Bio-accumulative Potential:** No data available.

**Mobility in Soil:** No data available.

## SECTION 13 - DISPOSAL CONSIDERATIONS



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**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and 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. This may include destructive techniques for waste and wastewater.

## SECTION 14 - TRANSPORTATION INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## SECTION 15 - REGULATORY INFORMATION

### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Busulfan:

|   |  |
|---|--|
| CERCLA/SARA 313 Emission reporting                        | : Not Listed   |
| California Proposition 65                                 | : carcinogen 2/27/1987<br>developmental toxicity<br>1/1/1989 |
| Standard for the Uniform Scheduling for Drugs and Poisons | : Schedule 4   |
| EU EINECS/ELINCS List                                     | : 200-250-2  |
| Australia (AICS)  | : Present  |

#### N,N- Dimethylacetamide:

|   |  |
|---|--|
| CERCLA/SARA 313 Emission reporting                                | : Not Listed   |
| California Proposition 65   | : Developmental toxicity<br>5/21/2010<br>male reproductive toxicity<br>5/21/10 |
| Standard for the Uniform Scheduling for Drugs and Poisons         | : Schedule 5<br>Schedule 6   |
| EU EINECS/ELINCS List   | : 204-826-4  |
| Australia (AICS)  | : Present  |
| Inventory - United States TSCA - Sect. 8(b)                       | : Present  |
| REACH - Annex XVII - Restrictions on Certain Dangerous Substances | : Use restricted.<br>See item 30.  |
| REACH - Toxic to Reproduction Category 2                          | : Present  |

#### Polyethylene glycol:

|                                    |              |
|------------------------------------|--------------|
| CERCLA/SARA 313 Emission reporting | : Not Listed |
| California Proposition 65          | : Not Listed |

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|  |                            |
|--|----------------------------|
| <b>Standard for the Uniform Scheduling for Drugs and Poisons</b> | : Schedule 2<br>Schedule 3 |
| <b>EU EINECS/ELINCS List</b>                                     | : Not Listed               |
| <b>Australia (AICS)</b>  | : Present                  |
| <b>Inventory - United States TSCA - Sect. 8(b)</b>               | : Present                  |

## SECTION 16 - OTHER INFORMATION

### Full text of H phrases and GHS classifications:

|         |   |
|---------|---|
| ATO4    | - Acute Toxicity (Oral) Category 4.   |
| Carc1B  | - Carcinogenicity Category 1B.  |
| STOT-R1 | - Specific Target Organ Toxicity Following Repeat Exposure Category 1.                                |
| RT1B    | - Reproductive toxicity Category 1B.  |
| GCM2    | - Germ Cell Mutagenicity Category 2.  |
| AA1     | - Acute aquatic toxicity Category 1.  |
| CA1     | - Chronic Aquatic Toxicity Category 1.  |
| H302    | - Harmful if swallowed.   |
| H341    | - Suspected of causing genetic defects.   |
| H350    | - May cause cancer.   |
| H360FD  | - May damage fertility. May damage the unborn child.  |
| H372    | - Causes damage to hematological and gastrointestinal systems through prolonged or repeated exposure. |
| H400    | - Very toxic to aquatic life.   |
| H410    | - Very toxic to aquatic life with long lasting effects.   |

### Abbreviations:

|           |   |
|-----------|---|
| ACGIH     | : American Conference of Governmental Industrial Hygienists               |
| AICS      | : Australian Inventory of Chemical Substances                             |
| AIHA      | : American Industrial Hygiene Association                                 |
| ANSI      | : American National Standards Institute                                   |
| CAS       | : Number Chemical Abstract Service Registry Number                        |
| CERCLA    | : Comprehensive Environmental Response Compensation and Liability Act     |
| CHAN      | : Chemical Hazard Alert Notice  |
| CHEMTREC  | : Chemical Transportation Emergency Center                                |
| DOT       | : Department of Transportation  |
| DSL       | : Domestic Substances List  |
| ECHA      | : European Chemicals Agency   |
| EINECS    | : European Inventory of Existing Commercial Chemical Substances           |
| ELINCS    | : European List of Notified Chemical Substances                           |
| EPA       | : Environmental Protection Agency   |
| GHS       | : Globally Harmonized System of Classification and Labelling of Chemicals |
| HEPA      | : High Efficiency Particulate Air (Filter)                                |
| HMIS      | : Hazardous Materials Identification System                               |
| IARC      | : International Agency for Research on Cancer                             |
| ICAO/IATA | : International Civil Aviation Organization/International Air Transport   |
| IMO       | : International Maritime Organization                                     |

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|       |   |
|-------|---|
| KOW   | : Octanol/Water Partition Coefficient                           |
| LEL   | : Lower Explosive Limit   |
| MSDS  | : Material Safety Data Sheet                                    |
| MSHA  | : Mine Safety and Health Administration                         |
| NA    | : Not Applicable, except in Section 14 where NA = North America |
| NE    | : Not Established   |
| NADA  | : New Animal Drug Application                                   |
| NAIF  | : No Applicable Information Found                               |
| NCI   | : National Cancer Institute                                     |
| NDSL  | : Non-Domestic Substances List                                  |
| NFPA  | : National Fire Protection Association                          |
| NIOSH | : National Institute for Occupational Safety and Health         |
| NPDES | : National Pollutant Discharge Elimination System               |
| NOS   | : Not Otherwise Specified                                       |
| NTP   | : National Toxicology Program                                   |
| OSHA  | : Occupational Safety and Health Administration                 |
| OEL   | : Occupational Exposure Limit                                   |
| PEL   | : Permissible Exposure Limit (OSHA)                             |
| RCRA  | : Resource Conservation and Recovery Act                        |
| RQ    | : Reportable Quantity   |
| RTECS | : Registry of Toxic Effects of Chemical Substances              |
| SARA  | : Superfund Amendments and Reauthorization Act                  |
| SDS   | : Safety Data Sheet   |
| STEL  | : Short Term Exposure Limit                                     |
| TLV   | : Threshold Limit Value (ACGIH)                                 |
| TPQ   | : Threshold Planning Quantity                                   |
| TSCA  | : Toxic Substances Control Act                                  |
| TWA   | : Time Weighted Average/8 Hours Unless Otherwise Noted          |
| UEL   | : Upper Explosive Limit   |
| UN    | : United Nations  |
| USP   | : United States Pharmacopeia                                    |
| WEEL  | : Workplace Environmental Exposure Level (AIHA)                 |
| WHMIS | : Workplace Hazardous Materials Information System              |

**Data Sources:** Information from published literature.

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall INTAS be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if INTAS has been advised of the possibility of such damages.