


**SECTION 1: PRODUCT IDENTIFICATION**

|                            |  |
|----------------------------|--|
| <b>PRODUCT NAME</b>        | <b>NITAZOXANIDE</b>  |
| <b>PRODUCT CODE</b>        | <b>3214</b>  |
| <b>SUPPLIER</b>            | <b>MEDISCA Inc.</b><br>Tel.: 1.800.932.1039   Fax.: 1.855.850.5855<br>661 Route 3, Unit C, Plattsburgh, NY, 12901<br>6641 N. Belt Line Road, Suite 130, Irving, TX, 75063<br><b>MEDISCA Pharmaceutique Inc.</b><br>Tel.: 1.800.665.6334   Fax.: 514.338.1693<br>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8<br>21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2<br><b>MEDISCA Australia PTY LTD</b><br>Tel.: 1.300.786.392   Fax.: 61.2.9700.9047<br>Unit 7, Heritage Business Park<br>5-9 Ricketty Street, Mascot, NSW 2020 |
| <b>EMERGENCY PHONE</b>     | CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300<br>NSW Poisons Information Centre: 131 126<br>National Chemical Emergency Centre 44(0)1235239670   |
| <b>RECOMMENDED USES</b>    | Manufacturing and Compounding  |
| <b>RESTRICTIONS ON USE</b> | Not applicable   |

**SECTION 2: HAZARDS IDENTIFICATION**

|   |  |   |
|---|--|---|
| <b>GHS CLASSIFICATION</b>   | Acute Toxicity - Oral (Category 4)<br>Acute Aquatic Toxicity (Category 3)            |   |
| <b>PICTOGRAM</b>  |   |   |
| <b>SIGNAL WORD</b>  | Warning  |   |
| <b>HAZARD STATEMENT(S)</b>  | Harmful if swallowed.<br>May cause an allergic reaction.<br>Harmful to aquatic life. |   |
| <b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b> | Not Applicable.  |   |
| <b>PRECAUTIONARY STATEMENT(S)</b>                                     | <b>Prevention</b>  | Wash thoroughly after handling.<br>Do not eat, drink or smoke when using this product.<br>Avoid breathing dust, fume, gas, mist, vapors, spray.<br>Contaminated work clothing must not be allowed out of the workplace.<br>Wear protective gloves.<br>Avoid release to the environment. |

**Response** IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth.  
IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.  
IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms call a poison center or medical professional.

**Storage** Not applicable

**Disposal** Dispose of contents and/or container in accordance with local regulations.

**HMIS CLASSIFICATION**

**Health Hazard**

1

**Flammability**

0

**Reactivity**

0

**Personal Protection**

G

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**CHEMICAL NAME** o-[N-(5-nitrothiazol-2-yl)carbamoyl]phenyl acetate

**BOTANICAL NAME** Not applicable

**SYNONYM** Not available

**CHEMICAL FORMULA** C<sub>12</sub>H<sub>9</sub>N<sub>3</sub>O<sub>5</sub>S

**CHEMICAL FAMILY** Not available

**CAS NUMBER** 55981-09-4

**ALTERNATE CAS NUMBER** Not applicable

**MOLECULAR WEIGHT** 307.2851

**COMPOSITION**

| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|---------------|------------|-----------|-------------|
| NITAZOXANIDE  | 55981-09-4 | 259-931-8 | 100         |

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

### SECTION 4: FIRST-AID MEASURES

**IN CASE OF EYE CONTACT** Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

**IN CASE OF SKIN CONTACT** Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

**IF SWALLOWED** Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

**IF INHALED** Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

**MEDICAL ATTENTION AND SPECIAL TREATMENT** Get emergency medical help.

**SYMPTOMS CAUSED BY EXPOSURE** Not expected to present a significant hazard under anticipated conditions of normal use.

### SECTION 5: FIREFIGHTING MEASURES

**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL** Not applicable

**FLAMMABLE PROPERTIES**

May be combustible at high temperature

**HAZARDOUS COMBUSTION PRODUCTS**

Under fire conditions, hazardous fumes will be present.

**SUITABLE & UNSUITABLE  
EXTINGUISHING MEDIA**
**Small fire:** dry chemical, CO<sub>2</sub> or water spray. **Large fire:** dry chemical, CO<sub>2</sub>, alcohol resistant foam or water spray. Do not get water inside containers.

**PROTECTIVE EQUIPMENT AND  
PRECAUTIONS FOR FIREFIGHTERS**

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**
**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**METHODS & MATERIAL FOR  
CONTAINMENT**

On land, sweep or shovel into suitable containers. Minimize generation of dust.

**CLEANUP PROCEDURE**

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**REFERENCE TO OTHER SECTIONS**

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

**SECTION 7: HANDLING AND STORAGE**
**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Store below 30°C. Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40 °C are acceptable.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**
**Chemical Name: NITAZOXANIDE CAS #: 55981-09-4**

|       | Country | Limit value-8 hours |                   | Limit value-Short Term |                   | IDLH | REL | Advisory | Notes |
|-------|---------|---------------------|-------------------|------------------------|-------------------|------|-----|----------|-------|
|       |         | ppm                 | mg/m <sup>3</sup> | ppm                    | mg/m <sup>3</sup> |      |     |          |       |
| OSHA  | USA     | N/L                 | N/L               | N/L                    | N/L               | N/L  | N/L | N/A      | N/A   |
| ACGIH | USA     | N/L                 | N/L               | N/L                    | N/L               | N/L  | N/L | N/A      | N/A   |
| NIOSH | USA     | N/L                 | N/L               | N/L                    | N/L               | N/L  | N/L | N/A      | N/A   |

|               |           |     |     |     |     |     |     |     |     |
|---------------|-----------|-----|-----|-----|-----|-----|-----|-----|-----|
| <b>WEEL</b>   | USA       | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| <b>HSIS</b>   | Australia | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| <b>HSE</b>    | UK        | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| <b>GESTIS</b> | N/L       | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

#### EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>.

#### PERSONAL PROTECTIVE EQUIPMENT

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

#### SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

#### BIOLOGICAL MONITORING

Not available

#### CONTROL BANDING

Not available

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### PHYSICAL STATE

Solid

#### DESCRIPTION

White to yellowish crystalline powder.

#### SOLUBILITY

Practically insoluble in water; very slightly soluble in alcohol; and soluble in N, N-dimethylacetamide.

#### ODOR

Not available.

#### FLAMMABILITY

May be combustible at high temperature

#### AUTO-IGNITION TEMPERATURE

Not available

#### BOILING POINT

Not available

#### DECOMPOSITION TEMPERATURE

Not available

#### EVAPORATION RATE

Not available

#### EXPLOSIVE LIMIT

Not available

#### FLASH POINT

Not available

#### log P (OCTANOL-WATER)

Not available

#### LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

#### MELTING/FREEZING POINT

Not available

#### PARTICLE CHARACTERISTICS

Not available

#### OXIDIZING PROPERTY

Not available

#### pH

Not available

#### RELATIVE DENSITY (WATER = 1)

Not available

#### SPECIFIC GRAVITY

Not available

#### UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

#### VAPOR DENSITY (AIR = 1)

10.61

#### VAPOR PRESSURE

Not available

#### VISCOSITY

Not available

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

|  |   |
|--|---|
| <b>REACTIVITY</b>                        | Not established   |
| <b>CHEMICAL STABILITY</b>                | Stable under recommended storage conditions   |
| <b>INCOMPATIBLE MATERIALS</b>            | Strong oxidants   |
| <b>HAZARDOUS DECOMPOSITION PRODUCTS</b>  | Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur |
| <b>HAZARDOUS POLYMERIZATION</b>          | Will not occur  |
| <b>POSSIBILITY OF HAZARDOUS REACTION</b> | Not established   |
| <b>CONDITIONS TO AVOID</b>               | Moisture, sunlight and extreme temperatures   |

## SECTION 11: TOXICOLOGICAL INFORMATION

|   |  |
|---|--|
| <b>ACUTE TOXICITY</b>                         | Oral: Rat: LD50: (mg/kg): 1000<br>Dermal: Rabbit: LD50: (mg/kg): Not available<br>Inhalation: Rat: LC50: (mg/L/4hr): Not available   |
| <b>SKIN CORROSION/IRRITATION</b>              | Due to lack of data the classification is not possible.  |
| <b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>      | Due to lack of data the classification is not possible.  |
| <b>RESPIRATORY SENSITIZATION</b>              | Based on available data, the classification criteria are not met.<br>Suspected respiratory sensitiser: The Toolbox profiler 'Respiratory sensitisation' gives an alert for respiratory sensitisation   |
| <b>SKIN SENSITIZATION</b>                     | Based on available data, the classification criteria are not met.<br>Suspected skin sensitiser: The Toolbox profiler 'Protein binding alerts for skin sensitization by OASIS v1.3' gives an alert for skin sensitisation   |
| <b>GERM CELL MUTAGENICITY</b>                 | Based on available data, the classification criteria are not met.<br>Suspected mutagen: The Toolbox profiler 'DNA alerts for AMES, MN and CA by OASIS v.1.3' gives an alert for mutagenicity; The Toolbox profiler 'in vitro mutagenicity (Ames test) alerts by ISS' gives an alert for mutagenicity; CAESAR Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Suspect Mutagen (moderate reliability); ISS Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (moderate reliability); KNN Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (moderate reliability) |
| <b>CARCINOGENICITY</b>                        | <b>OSHA</b> NITAZOXANIDE is not listed.<br><b>NTP</b> NITAZOXANIDE is not listed.<br><b>IARC</b> NITAZOXANIDE is not evaluated.<br><b>California Proposition 65</b> This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.   |
| <b>ADDITIONAL CARCINOGENICITY INFORMATION</b> | Based on available data, the classification criteria are not met.<br>Suspected carcinogen: The Toolbox profiler 'Carcinogenicity (genotox and nongenotox) alerts by ISS' gives an alert for carcinogenicity; ISS Carcinogenicity model in VEGA (Q)SAR platform predicts that the chemical is Carcinogen (moderate reliability)   |
| <b>REPRODUCTIVE TOXICITY</b>                  | Due to lack of data the classification is not possible.  |

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE** Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE** Due to lack of data the classification is not possible.

**ASPIRATION HAZARDS** Due to lack of data the classification is not possible.

**SIGNS AND SYMPTOMS OF EXPOSURE**

ROUTES OF EXPOSURE:  
Not available

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:  
Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:  
Not available

**POTENTIAL HEALTH EFFECTS**

**Inhalation** May be harmful if inhaled. May cause respiratory tract irritation.

**Ingestion** May be harmful if swallowed. Abdominal pain and diarrhoea.

**Skin** May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.

**Eyes** May cause eye irritation.

## SECTION 12: ECOLOGICAL INFORMATION

**ECOTOXICITY**

EC50: 48 Hr: Crustacea: (mg/L): Not available  
LC50: 96 Hr: Fish: (mg/L): 49.3\*  
EC50: 96 Hr: Green Algae: (mg/L): 3.51\*

**PERSISTENCE AND DEGRADABILITY** Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable

**BIOACCUMULATIVE POTENTIAL** Not available

**MOBILITY IN SOIL** Not available

**OTHER ADVERSE EFFECTS** Not available

**NOTES** This product is not intended to be released into the environment

\*Danish QSAR database

## SECTION 13: DISPOSAL CONSIDERATIONS

**DISPOSAL METHODS** Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

## SECTION 14: TRANSPORT INFORMATION

**UN PROPER SHIPPING NAME** Not dangerous good

**UN NUMBER** Not applicable

**CLASS** Not applicable

**PACKING GROUP** Not applicable

### AUSTRALIA

**HAZCHEM** Not applicable

**EU  
TRANSPORT IN BULK ACCORDING TO  
ANNEX II OF MARPOL 73/78 AND THE  
IBC CODE** Not Listed

**ENVIRONMENTAL HAZARDS** Not available

**SPECIAL SHIPPING INFORMATION** Not applicable

**SECTION 15: REGULATORY INFORMATION**
**UNITED STATES REGULATIONS**

| Chemical Name & CAS     | CERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR Part 372.65 | EPA 40 CFR Part 355 Appendix A | EPA 40 CFR Part 355 Appendix B | Pennsylvania | Right-to-know New Jersey | Massachusetts | California Prop 65 |
|-------------------------|--------------------------|-------------------------------------|--------------------------------|--------------------------------|--------------|--------------------------|---------------|--------------------|
| NITAZOXANIDE 55981-09-4 | N/L                      | N/L                                 | N/L                            | N/L                            | N/L          | N/L                      | N/L           | N/L                |

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

| Chemical Name & CAS     | Poisons and Therapeutic Goods | Therapeutic Goods Act | Code of Practices - Illicit Drug Precursors | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|-------------------------|-------------------------------|-----------------------|---|------------------|------------------------------------|-----------------------------------|
| NITAZOXANIDE 55981-09-4 | N/L                           | N/L                   | N/L   | N/L              | N/L                                | N/L                               |

N/L = Not Listed

**EU REGULATIONS**

| Chemical Name & CAS     | REACH ANNEX XVII | REACH ANNEX XIV | EC 1005/2009 | EC 850/2004 | EC 1107/2009 | PIC - Prior Informed Consent Regulation | EC 2012/18 |
|-------------------------|------------------|-----------------|--------------|-------------|--------------|---|------------|
| NITAZOXANIDE 55981-09-4 | N/L              | N/L             | N/L          | N/L         | N/L          | N/L                                     | N/L        |

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

**SUBJECT TO INTERNATIONAL AGREEMENT** Not applicable

**SECTION 16: OTHER INFORMATION**
**REFERENCES** Available upon request

**ABBREVIATIONS AND ACRONYMS**

**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

**LAST REVISION**

02/2023

**SUPERSEDES**

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://www.medisca.com)

**DISCLAIMER**

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

**SUPPLEMENTARY INFORMATION**

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.