



## Nitazoxanide Tablets, 500 mg Safety Data Sheet

This safety data sheet was developed based on regulations applicable to an industrial/occupational setting and may be applicable to Distribution personnel. This safety data sheet does not address consumer use; for any information relevant to consumer use or retail handling refer to the package label.

Effective date: 26Jan2020

Revision: 00

### SECTION 1: Identification

**Product:** Nitazoxanide  
**Identifier:** Tablets, 500 mg  
**Formula:** 2-acetyloxy-N-(5-nitro-2-thiazolyl)benzamide

**Recommended use:** Medicinal use for treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum* in patients 12 years of age and older

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

Romark, L.C.  
3000 Bayport Drive  
Suite 200  
Tampa, FL 33607  
USA

#### Emergency number:

Tel: (813) 282-8544  
Fax: (813) 282-1162

### SECTION 2: Hazard(s) Identification

**Classification:** Not classified  
**Hazard** None  
**pictograms: Signal** None  
**word: Hazard** None  
**statements:**

**Precautionary statements:** P261 + P341 Avoid breathing dust/ fume/ gas/ mist/ vapors/spray. Remove victim to fresh air.

P305 + P351 + P338 If in eyes, rinse cautiously with water and remove contact lenses.

P280 Wash thoroughly after handling.

**Other hazards:** No information available.

**Note:** This SDS has been prepared in accordance with standards for workplace safety. Warnings included and precautionary statements may not apply in all cases; your requirements may vary depending upon the potential for exposure in your workplace.

### SECTION 3: Composition/Information on Ingredients

Ingredient	CAS-No. or Unique identifier	%
Nitazoxanide	55981-09-4	<80%
Corn (maize) starch	9005-25-8	*
Pregelatinized corn starch	9005-25-8	*
Hydroxypropyl-methylcellulose	9004-65-3	*
Sucrose	50-1	*
Sodium starch glycolate	9063-38-1	*
Talc	14807-96-6	*
Magnesium stearate	557-04-0	*
Opadry (Soy lecithin, Polyvinyl alcohol, Xanthan gum, Titanium dioxide, D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, and FD&C Blue No.2 Aluminum Lake are found within Opadry)	No information available	*

\*Proprietary: In accordance with 29 CFR 1910.1200, the exact percentage composition of this product has been withheld as a trade secret.

### SECTION 4: First-Aid Measures

**Inhalation:** Not applicable.

**Eye contact:** In case of contact, immediately flush with water. Remove contact lenses. Get medical attention if irritation persists.

**Skin contact:** If excessive skin contact occurs, wash affected area with soap and water. Get medical attention if irritation develops or persists.

**Ingestion:** Seek medical attention in the event of overdose. Victim should be carefully observed and given symptomatic and supportive treatment. Gastric lavage may be appropriate soon after ingestion.

#### Important symptoms and effects, both acute and delayed

Abdominal pain, headache, chromaturia and nausea.

#### Indication of any immediate medical attention and special treatment needed

No information available

## SECTION 5: Fire-Fighting Measures

**Suitable extinguishing media:** Use extinguishing media appropriate for surrounding area.

**Specific hazards arising from the chemical:** No information available.

**Special protective equipment and precautions for fire-fighters:** Wear self-contained breathing apparatus and protective suit to prevent contact with skin and eyes.

## SECTION 6: Accidental Release Measures

### Personal precautions:

None for normal use.

### Methods and materials for containment and cleaning up:

Collect tablets and place in appropriate containers for disposal. Avoid generating dust.

## SECTION 7: Handling and Storage

### Precautions for safe handling:

Avoid contact with eyes. Avoid excessive contact with skin or clothing. Wash hands thoroughly after handling.

### Storage conditions:

Keep container tightly closed. This product is suitable for storage in any general pharmaceutical area. Store at 25°C (77°F); excursions permitted to 15°C- 30°C (59°F-86°F) (See USP Controlled Room Temperature).

## SECTION 8: Exposure Controls/Personal Protection

<b>Exposure limits:</b>	No information available
<b>Engineering controls:</b>	None required.
<b>Eye/Skin protection:</b>	Under normal conditions, special eye and skin protection not required.
<b>Inhalation protection:</b>	Under normal conditions, special ventilation not required. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**SECTION 9: Physical and Chemical Properties**

<b>Appearance:</b>	Round yellow, film-coated tablets debossed with 77 on one side and plain on the other side. Each tablet contains 500mg of nitazoxanide. The tablets are packaged in HDPE bottles of 12 and 30 tablets.
<b>Odor:</b>	Odorless
<b>Odor threshold:</b>	No information available
<b>pH:</b>	No information available
<b>Melting point/freezing point:</b>	No information available
<b>Initial boiling point and boiling range:</b>	No information available
<b>Flash point:</b>	No information available
<b>Evaporation rate:</b>	No information available
<b>Flammability:</b>	No information available
<b>Upper/lower flammability or explosive limits:</b>	No information available
<b>Vapor pressure:</b>	No information available
<b>Vapor density:</b>	No information available
<b>Relative density:</b>	No information available
<b>Solubility(ies):</b>	No information available
<b>Partition coefficient: n-octanol/water:</b>	No information available
<b>Auto-ignition temperature:</b>	No information available
<b>Decomposition temperature:</b>	No information available
<b>Viscosity:</b>	No information available

**SECTION 10: Stability and Reactivity**

<b>Reactivity:</b>	No hazardous polymerization will occur.
<b>Chemical stability:</b>	Contact with moisture or water cause formation of Tizoxanide (CAS 173903-47-4)
<b>Possibility of hazardous reactions:</b>	No information available
<b>Conditions to avoid:</b>	No information available
<b>Incompatible materials:</b>	No information available
<b>Hazardous decomposition products:</b>	No information available

## SECTION 11: Toxicological Information

<b>Acute toxicity:</b>	No information available
<b>Toxicity data:</b>	
ORL-RAT LD50:	>10,000 mg/kg
ORL-DOG LD50:	>10,000mg/kg
<b>Respiratory or skin sensitization:</b>	No information available
<b>Eye damage/irritation:</b>	No information available
<b>Skin corrosion/irritation:</b>	No information available
<b>Carcinogenicity:</b>	Long-term carcinogenicity studies have not been conducted.
<b>Reproductive toxicity:</b>	Nitazoxanide did not adversely affect male or female fertility in the rat at 2400 mg/kg/day (approximately 20 times the clinical adult dose adjusted for body surface area).
<b>Specific target organ toxicity (single exposure):</b>	No information available
<b>Specific target organ toxicity (repeated exposure):</b>	No information available
<b>Symptoms/injuries after inhalation:</b>	No information available
<b>Symptoms/injuries after eye contact:</b>	No information available
<b>Symptoms/injuries after ingestion:</b>	In clinical trials, the most common adverse reactions were abdominal pain, headache, chromaturia and nausea ( $\geq 2\%$ ).

## SECTION 12: Ecological Information (Non-mandatory)

<b>Ecotoxicity:</b>	No information available
<b>Persistence and degradability:</b>	No information available
<b>Bioaccumulative potential:</b>	No information available
<b>Mobility in soil:</b>	No information available
<b>Other adverse effects:</b>	No information available

## SECTION 13: Disposal Considerations (Non-mandatory)

<b>Disposal container(s):</b>	Dispose of in accordance with all applicable federal, state, and local environmental regulations.
<b>Disposal method(s):</b>	Handle contaminated packaging in same way as the substance itself. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.
<b>Special precautions:</b>	Not applicable

**SECTION 14: Transport Information (Non-mandatory)**

<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Land Transport (DOT): Not classified as dangerous Air Transport (IATA): Not classified as dangerous Sea Transport (IMDG): Not classified as dangerous
<b>Packing group number:</b>	Not applicable
<b>Environmental hazards:</b>	Not applicable
<b>Bulk transport guidance:</b>	Not applicable
<b>Special precautions:</b>	No special precautions

**SECTION 15: Regulatory Information (Non-mandatory)**

No additional information to provide.

**SECTION 16: Other Information**

No additional information to provide.

This safety data sheet has been drawn up to conform to the OSHA Hazard Communication Standard (HCS) 29 CFR 1910.1200(g).

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Romark, L.C. shall not be held liable for any damage resulting from handling or from contact with the above product.

The user is responsible for taking the measures required for compliance with local law and regulations. The information only concerns the product mentioned and does not guarantee the quality and completeness of the properties of the product nor if the product is used in combination with other products or in any other process. Prior to using this preparation for an experiment or a new application, the user should perform a material suitability and safety test him/herself.

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