

## Safety Data Sheet



### Section 1: Identification

#### Product identifier

##### Product Name

- **NidaGel Vaginal Gel, 0.75%**

##### Product Description

- Metronidazole Vaginal Gel is the intravaginal dosage form of the synthetic antibacterial agent, metronidazole, USP at a concentration of 0.75%.

#### Relevant identified uses of the substance or mixture and uses advised against

##### Recommended use

- Metronidazole Vaginal Gel is indicated in the treatment of bacterial vaginosis (formerly referred to as Haemophilus vaginitis, Gardnerella vaginitis, nonspecific vaginitis, Corynebacterium vaginitis, or anaerobic vaginosis).

##### Restrictions on use

- Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

#### Details of the supplier of the safety data sheet

##### Manufacturer

- Valeant Pharmaceuticals North America, LLC

Bridgewater, NJ 08807  
United States  
valeant.com

Telephone (General) • 1-800-321-4576

#### Emergency telephone number

##### Manufacturer

- 1-800-535-5053 - US - Infotrac

##### Manufacturer

- +1 352-323-3500 - International - Infotrac

*This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.*

### Section 2: Hazard Identification

#### UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

#### Classification of the substance or mixture

##### UN GHS

- Skin Irritation 2
- Skin Sensitization 1B
- Eye Irritation 2A
- Carcinogenicity 2
- Reproductive Toxicity 2

#### Label elements

##### UN GHS

#### WARNING



- Hazard statements**
- Causes serious eye irritation
  - Causes skin irritation
  - May cause an allergic skin reaction
  - Suspected of causing cancer.
  - Suspected of damaging fertility or the unborn child.

## Precautionary statements

- Prevention**
- Do not handle until all safety precautions have been read and understood.
  - Wash thoroughly after handling.
  - Use personal protective equipment as required.
  - Use only in accordance with label instructions and supplied prescribing information.

- Response**
- IF ON SKIN: Wash with plenty of soap and water.
  - If skin irritation or rash occurs: Get medical advice/attention.
  - 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 advice/attention.

- Storage/Disposal**
- Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. use before expiration date marked on carton and/or container.
  - Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

## Other hazards

### UN GHS

- No data available

## Section 3 - Composition/Information on Ingredients

### Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

### Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Metronidazole	CAS:443-48-1 EINECS:207-136-1	0.75%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Carc. 1A
Methylparaben	CAS:99-76-3 EINECS:202-785-7	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Propylparaben	CAS:94-13-3 EINECS:202-307-7	< 0.1%	UN GHS: NDA
Propylene glycol	CAS:57-55-6 EINECS:200-338-0	< 5%	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Carbomer	CAS:9003-01-4	< 5%	UN GHS: NDA
Edetate Disodium	CAS:6381-92-6	< 0.1%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	> 90%	UN GHS: NDA
Sodium hydroxide	CAS:1310-73-2 EINECS:215-185-5	< 1%	UN GHS: Skin Corr. 1A

## Section 4: First-Aid Measures

## Description of first aid measures

- |                   |   |
|-------------------|---|
| <b>Inhalation</b> | <ul style="list-style-type: none"> <li>Remove source of exposure. Seek medical attention if irritation or signs of toxicity occur. Provide symptomatic or supportive care as necessary.</li> </ul>  |
| <b>Skin</b>       | <ul style="list-style-type: none"> <li>Contact with skin can lead to irritation. If skin irritation occurs, discontinue use; remove source of exposure. Flush skin with copious amounts of water. Seek medical attention if irritation persists or signs of toxicity occur. Provide symptomatic or supportive care as necessary.</li> </ul> |
| <b>Eye</b>        | <ul style="list-style-type: none"> <li>If eye contact occurs, rinse eyes under gently running water for at least 15 minutes. Use sufficient force to open eyelids and roll eyes while flushing. Seek medical attention if irritation persists or signs of toxicity occur. Provide symptomatic or supportive care as necessary.</li> </ul>   |
| <b>Ingestion</b>  | <ul style="list-style-type: none"> <li>Remove source of exposure. Seek medical attention if irritation or signs of toxicity occur. Provide symptomatic or supportive care as necessary. If signs/symptoms develop, get medical attention.</li> </ul>  |

## Most important symptoms and effects, both acute and delayed

- No data available

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

### Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Additional details are provided on the product packaging and/or in the product insert.

## Section 5: Fire-Fighting Measures

### Extinguishing media

- |                                       |   |
|---------------------------------------|---|
| <b>Suitable Extinguishing Media</b>   | <ul style="list-style-type: none"> <li>Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.</li> </ul>  |
| <b>Unsuitable Extinguishing Media</b> | <ul style="list-style-type: none"> <li>No data available</li> </ul>   |
| <b>Firefighting Procedures</b>        | <ul style="list-style-type: none"> <li>As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and appropriate protective clothing.</li> </ul> |

### Special hazards arising from the substance or mixture

- |   |   |
|---|---|
| <b>Unusual Fire and Explosion Hazards</b> | <ul style="list-style-type: none"> <li>No data available</li> </ul>   |
| <b>Hazardous Combustion Products</b>      | <ul style="list-style-type: none"> <li>During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.</li> </ul> |

### Advice for firefighters

- No data available

## Section 6 - Accidental Release Measures

### Personal precautions, protective equipment and emergency procedures

- |                             |  |
|-----------------------------|--|
| <b>Personal Precautions</b> | <ul style="list-style-type: none"> <li>No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.</li> </ul>   |
| <b>Emergency Procedures</b> | <ul style="list-style-type: none"> <li>For bulk material spills: Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.</li> </ul> |

## Environmental precautions

- **LARGE SPILLS:** Prevent entry into waterways, sewers, basements or confined areas.

## Methods and material for containment and cleaning up

### Containment/Clean-up Measures

- Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers.  
Prevent runoff from entering drains, sewers, and streams.

## Other Information

- In the event of a release of bulk material, the user should determine if the release qualifies as reportable according to local, state, and federal regulations.

## Section 7 - Handling and Storage

### Precautions for safe handling

#### Handling

- No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use of impervious gloves is recommended if there is a potential for skin contact.

### Conditions for safe storage, including any incompatibilities

#### Storage

- Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. Use before expiration date marked on carton and/or container.

## Section 8 - Exposure Controls/Personal Protection

### Control parameters

#### Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines						
	Result	ACGIH	Canada Quebec	NIOSH	OSHA	Other Agency Information
Sodium hydroxide (1310-73-2)	Ceilings	2 mg/m3 Ceiling	2 mg/m3 Ceiling	2 mg/m3 Ceiling	Not established	Not established
	TWAs	Not established	Not established	Not established	2 mg/m3 TWA	Not established
Propylene glycol (57-55-6)	TWAs	Not established	Not established	Not established	Not established	10 mg/m3 TWA

### Exposure Limits Supplemental

#### ACGIH

- Sodium hydroxide (1310-73-2): **TLV Basis - Critical Effects:** (eye, skin and upper respiratory tract irritation)

### Exposure controls

#### Engineering Measures/Controls

- No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

#### Personal Protective Equipment

##### Respiratory

- No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, a NIOSH-certified air-purifying respirator equipped with HEPA -organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

##### Eye/Face

- No special personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye/face protection should be worn.

##### Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

**Skin/Body**

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

**Environmental Exposure Controls**

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

**Section 9 - Physical and Chemical Properties****Information on Physical and Chemical Properties**

Material Description			
Physical Form	Solid	Appearance/Description	Gel
Color	Clear, colorless to pale yellow.	Odor	Not relevant
Flammability			
Flash Point	Not flammable		

**Section 10: Stability and Reactivity****Reactivity**

- Stable under normal temperatures and pressures.

**Chemical stability**

- No data available

**Possibility of hazardous reactions**

- No data available

**Conditions to avoid**

- Avoid exposure to extreme heat or cold.

**Incompatible materials**

- No data available

**Hazardous decomposition products**

- No data available

**Section 11 - Toxicological Information****Information on toxicological effects**

Components		
Metronidazole (0.75%)	443-48-1	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 3 g/kg; <b>Behavioral:</b> <b>Somnolence (general depressed activity); Lungs, Thorax, or Respiration:</b> <b>Cyanosis;</b> <b>Nutritional and Gross Metabolic:</b> <b>Changes in Chemistry or Temperature:</b> <b>Body temperature decrease;</b> Ingestion/Oral-Man TDLo • 1030 mg/kg 8 Week(s); <b>Peripheral Nerve and Sensation:</b> <b>Paresthesia;</b> <b>Peripheral Nerve and Sensation:</b> <b>Structural change in nerve or sheath;</b> Ingestion/Oral-Woman TDLo • 12 mg/kg; <b>Sense Organs and Special Senses:</b> <b>Eye:</b> <b>Other;</b> <b>Behavioral:</b> <b>Tremor;</b> <b>Irritation:</b> Skin-Human • 0.75 % 3 Week(s) • Mild irritation; <b>Mutagen:</b> DNA damage • Unreported Route-Mouse • Fibroblast (Somatic cell) • 300 µmol/L
Methylparaben (< 0.1%)	99-76-3	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2100 mg/kg; <b>Irritation:</b> Skin-Rabbit • 0.1 mL 24 Hour(s) • Mild irritation; <b>Mutagen:</b> Cytogenetic analysis • Ingestion/Oral-Mouse • 25 g/kg 5 Day(s)-Intermittent
Propylparaben (< 0.1%)	94-13-3	<b>Acute Toxicity:</b> Ingestion/Oral-Mouse LD50 • 6332 mg/kg; <b>Mutagen:</b> Cytogenetic analysis • Unreported Route-Hamster • Ovary (Somatic cell) • 1.5 mmol/L 3 Hour(s)

Propylene glycol (< 5%)	57-55-6	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 20 g/kg; <b>Irritation:</b> Eye-Rabbit • 100 mg • Mild irritation; <b>Mutagen:</b> Cytogenetic analysis • Subcutaneous-Mouse • 8000 mg/kg; <b>Reproductive:</b> Intraperitoneal-Mouse TDLo • 100 mg/kg (11D preg); <i>Reproductive Effects: Effects on Fertility: Post-implantation mortality</i>
Carbomer (< 5%)	9003-01-4	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2500 mg/kg
Edetate Disodium (< 0.1%)	6381-92-6	<b>Mutagen:</b> Cytogenetic analysis • Unreported Route-Hamster • Lung (Somatic cell) • 200 mg/L
Water (> 90%)	7732-18-5	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • >90 mL/kg
Sodium hydroxide (< 1%)	1310-73-2	<b>Acute Toxicity:</b> Intraperitoneal-Mouse LD50 • 40 mg/kg; <b>Irritation:</b> Skin-Rabbit • 500 mg 24 Hour(s) • Severe irritation; <b>Mutagen:</b> Cytogenetic analysis • Unreported Route-Hamster • Ovary (Somatic cell) • 16 mmol/L

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Carcinogenicity 2
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Irritation 2
Skin sensitization	UN GHS • Skin Sensitizer 1B
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Toxic to Reproduction 2
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Irritation 2A

## Potential Health Effects

### Inhalation

- Acute (Immediate)** • May cause irritation.
- Chronic (Delayed)** • No data available

### Skin

- Acute (Immediate)** • Causes skin irritation. May cause skin sensitization. Symptoms include redness, and skin rash.
- Chronic (Delayed)** • Repeated and prolonged exposure may cause sensitization.

### Eye

- Acute (Immediate)** • Causes serious eye irritation.
- Chronic (Delayed)** • No data available

### Ingestion

- Acute (Immediate)** • May cause mild irritation.
- Chronic (Delayed)** • No data available

### Carcinogenic Effects

- Metronidazole has shown evidence of carcinogenic activity in a number of studies involving chronic oral administration in mice and rats. These studies have not been conducted with 0.75% metronidazole vaginal gel.

Carcinogenic Effects			
	CAS	IARC	NTP
Metronidazole	443-48-1	Group 2B-Possible Carcinogen	Reasonably Anticipated to be Human Carcinogen
Carbomer	9003-01-4	Group 3-Not Classifiable	Not Listed

**Reproductive Effects**

- No fetotoxicity or teratogenicity was observed when metronidazole was administered orally to pregnant mice at six times the recommended human dose (based on mg/m<sup>2</sup>); however, in a single small study where the drug was administered intraperitoneally, some intrauterine deaths were observed. Because animal reproduction studies are not always predictive of human response, and because metronidazole is a carcinogen in rodents, this drug should be used during pregnancy only if clearly needed.

**Other information**

- Refer to the product insert and/or prescribing information for additional acute and/or chronic health effects.

## Section 12 - Ecological Information

**Toxicity**

- No data available

**Persistence and degradability**

- No data available

**Bioaccumulative potential**

- No data available

**Mobility in Soil**

- No data available

**Other adverse effects**

## Section 13 - Disposal Considerations

**Waste treatment methods****Product waste**

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

**Packaging waste**

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

## Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

**Special precautions for user**

- No data available

**Transport in bulk according to Annex II of MARPOL 73/78**

- No data available

## and the IBC Code

## Section 15 - Regulatory Information

### Safety, health and environmental regulations/legislation specific for the substance or mixture

**SARA Hazard Classifications** • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Propylene glycol	57-55-6	Yes	Yes	Yes
Edetate Disodium	6381-92-6	Yes	No	No
Methylparaben	99-76-3	Yes	Yes	Yes
Propylparaben	94-13-3	Yes	Yes	Yes
Carbomer	9003-01-4	Yes	No	Yes
Metronidazole	443-48-1	Yes	Yes	No
Sodium hydroxide	1310-73-2	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

## Canada

### Labor

#### Canada - WHMIS - Classifications of Substances

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Propylene glycol	57-55-6	Uncontrolled product according to WHMIS classification criteria
• Sodium hydroxide	1310-73-2	E (including 0.04% in aqueous solution, 0.08%, 0.4% in aqueous solution, 2%, 2.5%, 4% in aqueous solution, 5%, 10%, 16%, 20%, 40%, 50% in aqueous solution, 8.7N)
• Edetate Disodium	6381-92-6	Uncontrolled product according to WHMIS classification criteria
• Metronidazole	443-48-1	D2A
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Carbomer	9003-01-4	Not Listed

#### Canada - WHMIS - Ingredient Disclosure List

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Propylene glycol	57-55-6	1 %
• Sodium hydroxide	1310-73-2	1 %
• Edetate Disodium	6381-92-6	Not Listed
• Metronidazole	443-48-1	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer	9003-01-4	Not Listed

## Europe



**Other****EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification**

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	C; R35
• Edetate Disodium	6381-92-6	Not Listed
• Metronidazole	443-48-1	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer	9003-01-4	Not Listed

**EU - CLP (1272/2008) - Annex VI - Table 3.2 - Concentration Limits**

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	5%≤C: C; R:35 2%≤C<5%: C; R:34 0.5%≤C<2%: Xi; R:36/38
• Edetate Disodium	6381-92-6	Not Listed
• Metronidazole	443-48-1	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer	9003-01-4	Not Listed

**EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling**

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	C R:35 S:(1/2)-26-37/39-45
• Edetate Disodium	6381-92-6	Not Listed
• Metronidazole	443-48-1	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer	9003-01-4	Not Listed

**EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases**

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	S:(1/2)-26-37/39-45
• Edetate Disodium	6381-92-6	Not Listed
• Metronidazole	443-48-1	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer	9003-01-4	Not Listed

**United States****Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	1000 lb final RQ; 454 kg final RQ
• Edetate Disodium	6381-92-6	Not Listed
• Metronidazole	443-48-1	Not Listed

• Water	7732-18-5	Not Listed
• Carbomer	9003-01-4	Not Listed

## United States - California

### Environment

#### U.S. - California - Proposition 65 - Carcinogens List

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Metronidazole	443-48-1	carcinogen, initial date 1/1/88
• Water	7732-18-5	Not Listed
• Carbomer	9003-01-4	Not Listed

#### U.S. - California - Proposition 65 - Developmental Toxicity

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Metronidazole	443-48-1	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer	9003-01-4	Not Listed

#### U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Metronidazole	443-48-1	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer	9003-01-4	Not Listed

#### U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Edetate Disodium	6381-92-6	Not Listed
• Metronidazole	443-48-1	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer	9003-01-4	Not Listed

## Section 16 - Other Information

### Last Revision Date

- 13/April/2015

### Preparation Date

- 13/April/2015

### Disclaimer/Statement of Liability

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