



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name

- **Arestin® (minocycline hydrochloride powder)**

Product Code

- NDC 65976-100-1; NDC 65976-100-12; NDC 65976-100-24

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

Recommended use

- Oral care. ARESTIN® may be used as part of a periodontal maintenance program which includes good oral hygiene, and scaling and root planing.

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

- Acute Toxicity Oral 5
Reproductive Toxicity 1
Carcinogenicity 2

Label elements

UN GHS

DANGER



- Hazard statements** • May be harmful if swallowed
May damage fertility or the unborn child.
Suspected of causing cancer.

Precautionary statements

- Prevention** ● Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash thoroughly after handling.
- Response** ● IF exposed or concerned: Get medical advice/attention.
- Storage/Disposal** ● Keep tightly closed. Store at controlled room temperature 20-25°C/68-77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before 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
Minocycline hydrochloride	CAS:13614-98-7 EINECS:237-099-7	20% TO 30%	UN GHS: Acute Tox. Oral 5
Poly(DL-Lactide-Co-Glycolide)	CAS:26780-50-7	65% TO 80%	UN GHS: NDA

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

- Inhalation** ● No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention.
- Skin** ● Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.
- Eye** ● 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.
- Ingestion** ● No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

- Notes to Physician** ● Hypersensitivity reactions that included, but were not limited to anaphylaxis, angioneurotic edema, urticaria, rash, swelling of the face, and pruritus have been

reported.

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.
LARGE FIRE: Water spray, fog or regular foam.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known.

Hazardous Combustion Products • None known.

Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions • 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.

Emergency Procedures • Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Avoid generating dust.
Moisten material first to prevent dust and sweep spilled substances into containers.

Section 7 - Handling and Storage

Precautions for safe handling

Handling • Minimize dust generation and accumulation. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage • Keep tightly closed. Store at controlled room temperature 20-25°C/68-77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- No regulatory limits have been established. Good industrial hygiene practices should be followed to reduce exposures as much as possible.

Exposure controls**Engineering Measures/Controls**

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment**Respiratory**

- In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. 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

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.

Hands

- Wear appropriate gloves.

Skin/Body

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

General Industrial Hygiene Considerations

- Wash thoroughly after handling.

Environmental Exposure Controls

- No data available

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

Material Description			
Physical Form	Solid	Appearance/Description	Powder
Color	Yellow to dark yellow.	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	Not relevant	Melting Point	No data available
Decomposition Temperature	Not relevant	pH	Not relevant
Specific Gravity/Relative Density	Not relevant	Bulk Density	Not relevant
Water Solubility	Soluble	Viscosity	Not relevant
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

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

Components		
Minocycline hydrochloride (20% TO 30%)	13614-98-7	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2380 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Acute Toxicity - Oral 5
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 • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Toxic to Reproduction 1
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

Potential Health Effects**Inhalation**

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

Skin

- Acute (Immediate)** • Not expected to cause skin irritation.
- Chronic (Delayed)** • No data available.

Eye

- Acute (Immediate)** • May cause mild irritation.

Chronic (Delayed)	No data available.
Ingestion	
Acute (Immediate)	May cause acute toxicity in doses exceeding recommendation.
Chronic (Delayed)	No data available.
Carcinogenic Effects	Dietary administration of minocycline in long-term tumorigenicity studies in rats resulted in evidence of thyroid tumor production. Minocycline has also been found to produce thyroid hyperplasia in rats and dogs. In addition, there has been evidence of oncogenic activity in rats in studies with a related antibiotic, oxytetracycline (i.e., adrenal and pituitary tumors).
Reproductive Effects	THE USE OF DRUGS OF THE TETRACYCLINE CLASS DURING TOOTH DEVELOPMENT (LAST HALF OF PREGNANCY, INFANCY, AND CHILDHOOD TO THE AGE OF 8 YEARS) MAY CAUSE PERMANENT DISCOLORATION OF THE TEETH (YELLOW-GRAY BROWN). This adverse reaction is more common during long-term use of the drugs, but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Evidence of embryotoxicity has also been noted in animals treated early in pregnancy.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

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
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA

IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA
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Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

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	EU EINECS	TSCA
Minocycline hydrochloride	13614-98-7	Yes	No
Poly(DL-Lactide-Co-Glycolide)	26780-50-7	No	No

United States - California

Environment

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

• Poly(DL-Lactide-Co-Glycolide)	26780-50-7	Not Listed
• Minocycline hydrochloride	13614-98-7	Not Listed

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

• Poly(DL-Lactide-Co-Glycolide)	26780-50-7	Not Listed
• Minocycline hydrochloride	13614-98-7	developmental toxicity, initial date 1/1/92 (internal use)

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

• Poly(DL-Lactide-Co-Glycolide)	26780-50-7	Not Listed
• Minocycline hydrochloride	13614-98-7	Not Listed

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

• Poly(DL-Lactide-Co-Glycolide)	26780-50-7	Not Listed
• Minocycline hydrochloride	13614-98-7	Not Listed

Section 16 - Other Information

Last Revision Date • 16/June/2015

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