

MATERIAL SAFETY DATA SHEET

SECTION 1 – COMPANY AND PRODUCT IDENTIFICATION

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Telephone: +31-(0)348-565858
Fax: +31-(0)348-565454

Product name: Metrobactin 500 mg tablets
Substance name: metronidazole
Category: Antimicrobial

SECTION 2 – COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Metronidazole	443-48-1	250.0 mg
Microcrystalline cellulose	9004-34-6	
Sodium starch glycolate, Type A	9063-38-1	
Hydroxypropylcellulose	9004-64-2	
Magnesium stearate	557-04-0	
Yeast (dried)	n.a.	
Chicken flavour	n.a.	

SECTION 3 – HAZARDS IDENTIFICATION

Route of entry: Eye/Skin contact, accidental ingestion

**Chemical Listing as
Carcinogen**

NTP: Yes

IARC: No

OSHA: No

Note: Metronidazole has confirmed mutagenic and genotoxic properties in laboratory animals as well as in humans. Metronidazole is a confirmed carcinogen in laboratory animals and has possible carcinogenic effects in humans. However, there is inadequate evidence in humans for the carcinogenicity of metronidazole.

SECTION 4 – EMERGENCY & FIRST AID MEASURES

Metronidazole has confirmed mutagenic and genotoxic properties in laboratory animals as well as in humans. Metronidazole is a confirmed carcinogen in laboratory animals and has possible carcinogenic effects in humans. However, there is inadequate evidence in humans for the

carcinogenicity of metronidazole. Impervious gloves should be worn during administration of the product to avoid skin contact with the product.

To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands thoroughly after handling the tablets.

SECTION 5 – FIRE FIGHTING MEASURES

Fire and Explosion Data

Closed Cup Flash Point:	NE
Open Cup Flash Point:	NE
Fire Point:	NE
Autoignition:	NE
Lower Explosion Limit:	NE
Upper Explosion Limit:	NE

Fire Fighting Instructions: SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Fire Fighting Equipment: Wear self-containing breathing apparatus and protective clothing.

Hazardous Combustion Products: May be combustible at high temperature. Products of combustion are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂...).

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Clean-Up: Use appropriate tools to put the spilled solid in a convenient waste disposal container.

SECTION 7 – HANDLING AND STORAGE

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Storage Conditions: Non special storage conditions.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protective

Equipment

Eye Protection: None

Hand Protection: Were impervious gloves when handling the product.

Respiratory

Protection: With satisfactory ventilation, respiratory protection is usually not required.

Skin Protection: Were impervious gloves when handling the product.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Form/

Appearance: Light brown with brown spots, round and convex tablet with a cross-shaped break line on one side.

Chemical group: Antibacterials for systemic use - (nitro) imidazole derivatives.

SECTION 10 – STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: None

Hazardous

Polymerisation: Will not occur.

SECTION 11 – TOXICOLOGY INFORMATION

Signs & Symptoms of Exposure & Overexposure: This product is intended for therapeutic use only when prescribed by a veterinarian. Potential adverse reactions from prescribed doses in humans are described in the package insert.

Medical Conditions

Aggravated by

Exposure: Hypersensitivity to any of the ingredients.

SECTION 12 – TRANSPORTATION INFORMATION

UN/NA Number: NA

U.S. DOT Hazard Class: NA

Proper Shipping Name: NA

Shipping Label: NA

SECTION 13 – DISPOSAL INFORMATION

Disposal procedure: Treatment, storage, transportation, and disposal must be in accordance with applicable national and local regulations.