



Synfine Drugs
Pvt. Ltd

MATERIAL SAFETY DATA SHEET
(according to 1907/2006/EC, Article 31)

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE SUPPLIER	
Product name	METRONIDAZOLE
Product use	Treatment for antibiotic and parasite-fighting.
Manufacturer's name	Synfine Drugs Private Limited
Address	Survey. No. 637,637/A1, 637/AA2, 659, 660E, Temple Road, Bonthapally (Village), Gummadidala (Mandal), Sangareddy (Dist.)- 502313, Telangana, India
Tel No:	04023095094
FaxNo:	--
2. HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
Classification according to Regulation (EC) No 1272/2008	
Eye Damage.1, H318 Causes serious eye damage.	
	
Acute toxicity.4, H302 Harmful if swallowed.	
Skin Irritation.2, H315 Causes skin irritation.	
Aquatic Chronic. 3, H412 Harmful to aquatic life with long lasting effects.	
2.2 Label elements	
Labeling according to Regulation (EC) No 1272/2008	
The substance Sodium Phenylbutyrate is classified and labeled according to the CLP regulation	
Hazard pictograms	
	
Signal Word	Warning



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Hazard Statements:	
H302	Harmful if swallowed in large quantities
H315	Causes skin irritation
H318	Causes serious eye damage
H412	Harmful to aquatic life with long lasting effects.
Precautionary Statements:	
P280	Wear protective gloves / eye protection / face protection
P301+P312	If swallowed: call a poison center / doctor if you feel unwell.
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a poison center / doctor.
P321	Specific treatment(see on this label)
P501	Dispose of contents / container in accordance with local / regional / national / international regulations.
2.3 Other hazards	
Results of PBT and vPvB assessment	
PBT: Not applicable	
vPvB: Not applicable	

3. COMPOSITION / INFORMATION ON INGREDIENTS	
Synonyms	METRONIDAZOLE
Molecular Formula	C ₆ H ₉ N ₃ O ₃
Molecular Weight	171.2 g/mol
CAS Number	[443-48-1]
Additional Information: For the wording of the listed hazard phrases refer to Section 16.	



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4. FIRST-AID MEASURES

General Information	Symptoms of poisoning may occurs even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.
If Inhaled	Supply fresh air; consult doctor in case of complaints.
In case of skin contact	Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.
In case of eye contact	Rinse opened eye for several minutes under running water. Then consult a doctor.
If swallowed	Rinse mouth. Do not induce vomiting. Seek medical treatment.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use fire extinguishing methods suitable for surrounding conditions.
Fire / Explosion Hazards:	Formation of toxic gases is possible during heating or in case of fire. Use water spray to cool fire-exposed containers

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Wear protective equipment. Keep unprotected persons away.

Environmental precautions: Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers / surface or ground water.

Methods and Material for Containment and C: Use neutralizing agent. Dispose of contaminated material as waste according to item 13.

7. HANDLING AND STORAGE

Precautions for safe handling:

Remove dust thoroughly. Store in cool, dry place in tightly closed receptacles.

Conditions for safe Storage:

Requirements to be met by storerooms and receptacles:

Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA.

Keep container in a well-ventilated place. Keep away from sources of ignition and heat.

Information about storage in one common storage facility: Store away from foodstuffs.

Further information about storage conditions: Keep container tightly sealed.



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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with the skin. Avoid contact with the eyes and skin.

Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.

Hand protection: The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374



Protective gloves

Eye protection: Wear tightly sealed goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	A white to pale yellow crystalline powder.
Physical state	Solid
Colour	slightly yellow
Odour	Odourless
pH & pKa	No data available
Melting point:	No data available
Boiling point:	No data available
Water at 20°C	Not more than 0.5%
Partition coefficient n-octanol/water (log value)	No data available
Density at 20°C	No data available



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pKa	No data available	
Flash point:	No data available	
Ignition temperature:	No data available	
Internal explosion limit:	No data available	
Upper explosion limit:	No data available	
Solubility:	Ethanol, Methylene Chloride, Acetone	
10. STABILITY AND REACTIVITY		
Chemical stability:	Stable under normal conditions	
Conditions to avoid:	Heat	
Materials to avoid:	Strong oxidizing agents	
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers.	
11. TOXICOLOGICAL INFORMATION		
Acute toxicity: Harmful if swallowed		
LD/LC50 values relevant for classification:		
Oral	LD50	3 g/kg (rat)
	LD50	3800 mg/kg (mouse)
	LD50 (Intraperitoneal)	870 mg/kg (rat)
Skin corrosion/irritation: Causes skin irritation		
Serious eye damage/irritation: Causes serious eye damage		
12. ECOLOGICAL INFORMATION		
12.1 Toxicity:		
Aquatic toxicity:		
LC-50 96 Hours	>180 mg/L (Shrimp)	
LC-50 96 Hours	>1060 mg/L (Sheepshead Minnow)	



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12.2 Persistence and degradability: 3.78 (BCF)

12.3 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.4 Other adverse effects

Remarks: Harmful to fish

Additional ecological information:

General notes:

Water hazard class 2 (German Regulation) (Assessment by list): hazardous for water.

Do not allow product to reach ground water, water course or sewage system.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Danger to drinking water if even small quantities leak into the ground.

Harmful to aquatic organisms.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Uncleaned Packaging: Dispose of in accordance with national regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I Substance is not listed.

Chemical safety assessment: A Chemical Safety Assessment has not been carried out



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16. OTHER INFORMATION

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

Abbreviations and Acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1



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Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

Sources

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

Data compared to the previous version altered. All sections have been updated.

PREPARED BY: QC


25/07/2016

APPROVED BY: QA


25/07/2016

