

Safety Data Sheet

METRO I.V.™ (METRONIDAZOLE INJECTION USP)

SDS Revision Date:

05/13/2015

1. Identification

1.1. Product identifier

Product Identity METRO I.V.™ (METRONIDAZOLE INJECTION USP)
Alternate Names METRO I.V.™ (METRONIDAZOLE INJECTION USP)

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

Intended use See Technical Data Sheet.
Application Method See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet

Company Name B. Braun Medical Inc.
2525 McGaw Ave
Irvine, CA 92614
Emergency (800) 854-6851
Customer Service: B. Braun Medical Inc. (949) 660-2000

2. Hazard(s) identification

2.1. Classification of the substance or mixture

Carc. 1B;H350 May cause cancer.

2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.



Danger

H350 May cause cancer.

[Prevention]:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P281 Use personal protective equipment as required.

[Response]:

P308+313 IF exposed or concerned: Get medical advice / attention.

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[Storage]:

P405 Store locked up.

[Disposal]:

P501 Dispose of contents / container in accordance with local / national regulations.

3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Metronidazole CAS Number: 0000443-48-1	0.10 - 1.0	Muta. 2;H341 Carc. 1B;H350 STOT RE 2;H373	[1]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

*The full texts of the phrases are shown in Section 16.

4. First aid measures

4.1. Description of first aid measures

General	Remove from exposure. Remove contaminated clothing. Person developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.
Inhalation	Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.
Eyes	Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.
Ingestion	If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Overview	Metro I.V.™ is a sterile, nonpyrogenic, isotonic buffered solution intended to be infused intravenously by prescription of a physician. This drug product is packaged in individual single dose containers of I.V. administration. It is not anticipated that employees will be exposed to its contents during handling or administration, and thus, chronic exposure of employees to this product is extremely unlikely. Furthermore, the concentration of Metronidazole in the product is only 0.50%. At this low concentration, accidental exposure to this product does not represent a health hazard.
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Eye and Skin Contact to concentrated Metronidazole may produce irritation, hypersensitivity (urticaria, rash, and flushing), and general discomfort. Inhalation of the active ingredient of this product may produce irritation and discomfort and possibly an allergic reaction. Ingestion of product presentation makes this route of exposure extremely unlikely. However, ingestion of the active ingredient is known to produce irritation and possibly an allergic reaction. Persons allergic to metronidazole should especially avoid contact with the solution. As some persons may develop anaphylactic hypersensitivity to the active ingredient, precautions should be taken when handling the product to minimize repeated exposure. Metronidazole has been shown to be carcinogenic in mice and rats and is listed as a carcinogen by the International Agency for Research on Cancer (I.A.R.C. Vol. 13, 1977, p 113-122). Possible cancer hazard. Contains an ingredient which may cause cancer based on animal data (See Section 3 and Section 15 for each ingredient). Risk of cancer depends on duration and level of exposure. See section 2 for further details.

5. Fire-fighting measures

5.1. Extinguishing media

In case of fire, use extinguishing media appropriate for surrounding material.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Thermal decomposition of the solution may release water vapor and oxides of carbon, nitrogen and phosphorous. Thermal decomposition of the plastic containers may release noxious gases such as CO₂ and CO.

5.3. Advice for fire-fighters

Heat buildup may cause container rupture and spillage of contents. Use water mist to cool containers. As with all fires, all personnel should be evacuated from fire area. Firefighters should use self-contained breathing apparatus and protective clothing. No unusual fire or explosion hazards are associated with the product.

ERG Guide No. ----

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up

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In case of spill or leak, clean up spill with paper towels or other absorbent material. Place spillage and waste absorbent material in appropriate container for disposal. Do not flush spill into sewage system. Dispose of waste in accordance with all Federal, State and Local regulations.

7. Handling and storage

7.1. Precautions for safe handling

See section 2 for further details. - [Prevention]:

7.2. Conditions for safe storage, including any incompatibilities

Store in dry, cool storage facilities designed to store pharmaceuticals.

Incompatible materials: No data available.

See section 2 for further details. - [Storage]:

7.3. Specific end use(s)

No data available.

8. Exposure controls and personal protection

8.1. Control parameters

Exposure

CAS No.	Ingredient	Source	Value
0000443-48-1	Metronidazole	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

Carcinogen Data

CAS No.	Ingredient	Source	Value
0000443-48-1	Metronidazole	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: Yes
		IARC	Group 1: No; Group 2a: No; Group 2b: Yes; Group 3: No; Group 4: No;

8.2. Exposure controls

Respiratory

No respiratory protection or special ventilation is required when handling these products.

Eyes

Safety Glasses.

Skin

Persons handling these products should wear protective clothing such as laboratory coats or uniforms. Protective gloves should be worn when exposure is expected, as when cleaning up a spill, but are not required during the normal handling of the product. In general, all contact with Metro I.V. solution should be avoided.

Engineering Controls

Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to

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maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

Other Work Practices No special ventilation required. Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details. - [Prevention]:

9. Physical and chemical properties

Appearance	Clear, pale yellow Liquid
Odor	Very Slight
Odor threshold	Not Measured
pH	Not Measured
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not Measured Upper Explosive Limit: Not Measured
Vapor pressure (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	Not Measured
Solubility in Water	Not Measured
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Not Measured

9.2. Other information

No other relevant information.

10. Stability and reactivity

10.1. Reactivity

Hazardous Polymerization will not occur.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

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No data available.

10.4. Conditions to avoid

Avoid overheating product, as plastic bags may rupture and spill contents.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Thermal decomposition of the solution may release water vapor and oxides of carbon, nitrogen and phosphorous.

Thermal decomposition of the plastic containers may release noxious gases such as CO₂ and CO.

11. Toxicological information

Acute toxicity

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Metronidazole - (443-48-1)	No data available	No data available	No data available	No data available	No data available

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	1B	May cause cancer.
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

12. Ecological information

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12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Metronidazole - (443-48-1)	Not Available	Not Available	Not Available

12.2. Persistence and degradability

There is no data available on the preparation itself.

12.3. Bioaccumulative potential

Not Measured

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

13. Disposal considerations

13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air Class: Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
14.5. Environmental hazards			
IMDG	Marine Pollutant: No		
14.6. Special precautions for user			

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No further information

15. Regulatory information

Regulatory Overview	The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.
Toxic Substance Control Act (TSCA)	All components of this material are either listed or exempt from listing on the TSCA Inventory.
WHMIS Classification	D2A
US EPA Tier II Hazards	Fire: No Sudden Release of Pressure: No Reactive: No Immediate (Acute): No Delayed (Chronic): Yes

EPCRA 311/312 Chemicals and RQs:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 302 Extremely Hazardous:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):

Metronidazole

Proposition 65 - Developmental Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

New Jersey RTK Substances (>1%) :

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Pennsylvania RTK Substances (>1%) :

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

16. Other information

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The information provided in this SDS is intended to be used in the handling of this material in the work place. This SDS is not a substitute for the direction for use of product literature that may accompany the finished product. All information contained in this SDS has been assembled from other published documents and are assumed to be accurate. In the event of an adverse incident associated with this material, this SDS is not intended to be a substitute for consultation with appropriately qualified personnel.

The full text of the phrases appearing in section 3 is:

H341 Suspected of causing genetic defects.

H350 May cause cancer.

H373 May cause damage to organs through prolonged or repeated exposure.

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

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