

**MATERIAL SAFETY DATA SHEET****SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION****Company Name**

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Substance

METRONIDAZOLE

Trade Names/Synonyms

1H-IMIDAZOLE-1-ETHANOL, 2-METHYL-5-NITRO-;
IMIDAZOLE-1-ETHANOL,
2-METHYL-5-NITRO-; 2-METHYL-5-NITRO-1H-IMIDAZOLE-1-ETHANOL;
2-METHYL-5-NITROIMIDAZOLE-1-ETHANOL;
1-(2-HYDROXYETHYL)-2-METHYL-5-NITROIMIDAZOLE;
1-(BETA-ETHYLOL)-2-METHYL-5-NITRO-3-AZAPYRROLE;
1-HYDROXYETHYL-2-METHYL-5-NITROIMIDAZOLE;
1-(BETA-HYDROXYETHYL)-2-METHYL-5-NITROIMIDAZOLE;
2-METHYL-5-NITRO-1-IMIDAZOLE-ETHANOL;
METHYL-NITROIMIDAZOLE-1-ETHANOL; IMIDAZOLE,
1-(2-HYDROXYETHYL)-2-METHYL-5-NITRO; BAYER 5360; CLONT;
FLAGYL(R) I.V. RTU(R) (METRONIDAZOLE INJECTION, USP);
KLION; ORVAGIL; RP 8823; TRIVAZOL; VAGIMID; C6H9N3O3; OHS72529;
RTECS NI5600000

Chemical Family

Imidazolyl, nitro, hydroxyls, aliphatic

SECTION 2 - COMPOSITION & INFORMATION ON INGREDIENTS

| | | |
|-----------------------|---|-----------------|
| Name of the substance | : | METRONIDAZOLE |
| CAS Number | : | 443-48-1 |
| EC Number (EINECS) | : | 207-136-1 |
| Percentage | : | 100.0 |
| Change In Appearance | : | light-sensitive |

SECTION 3 - HAZARDS IDENTIFICATION

| | | |
|--------------|---|-------|
| NFPA Ratings | : | (0-4) |
| Health | : | 1 |
| Fire | : | 1 |
| Reactivity | : | 0 |

Physical Appearance

Color white, off-white or yellow crystalline powder

Odor

Faint odor

Major Health Hazards suspect cancer hazard (in animals)

Inhalation

Short term exposure: No information is available

Long term exposure: No information is available,

Irritation

Long term exposure: No information is available

Eye contact

Short term exposure: No information on significant adverse effects

Long term exposure: No information is available

Ingestion

Short term exposure: Nausea, vomiting, disorientation

Long term exposure: Same as effects reported in short term exposure, rash, metallic taste, diarrhoea, stomach pain, headache, dizziness, fainting, joint pain, enlargement of breasts in males, infertility, blood disorders, nerve damage, effects on the brain, convulsions, cancer

CARCINOGEN STATUS

| | |
|------|---|
| OSHA | N |
| NTP | Y |
| IARC | Y |

SECTION 4 - FIRST AID MEASURES**Inhalation**

Remove from exposure immediately. Use a bag valve mask or similar device to perform artificial respiration (rescue breathing) if needed. Get medical attention.

Skin Contact

Remove contaminated clothing, jewelry, and shoes immediately. Wash with soap or mild detergent and large amounts of water until no evidence of chemical remains (at least 15-20 minutes). Get medical attention, if needed.

Eye Contact

Wash eyes immediately with large amounts of water or normal saline, occasionally lifting upper and lower lids, until no evidence of chemical remains. Get medical attention immediately.

Ingestion

If vomiting occurs, keep head lower than hips to help prevent aspiration. Get medical attention, if needed.

SECTION 5 - FIRE FIGHTING MEASURES

Fire and Explosion Hazards

Slight fire hazard

Extinguishing Media

regular dry chemical, carbon dioxide, water, regular foam

Large fires: Use regular foam or flood with fine water spray.

Fire Fighting

Move container from fire area if it can be done without risk. Do not scatter spilled material with high-pressure water streams. Dike for later disposal.

Use extinguishing agents appropriate for surrounding fire. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Water Release

As per National regulations for Water & Sewage.

Occupational Release

Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers. Keep unnecessary people away, isolate hazard area and deny entry.

SECTION 7 - HANDLING AND STORAGE

Handle in accordance with all current regulations and standards. Keep separated from incompatible substances.

Storage- Store in well closed light resistant container.

SECTION 8 - EXPOSURE CONTROLS & PERSONAL PROTECTION

Exposure Limits :

No occupational exposure limits established.

Ventilation

Provide local exhaust or process enclosure ventilation system. Ensure compliance with applicable exposure limits.

Eye Protection

Wear splash resistant safety goggles with a face shield. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

Clothing

Wear appropriate chemical resistant clothing.

Gloves

Wear appropriate chemical resistant gloves.

Respirator

Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use. Any supplied-air respirator with a full face piece that is operated in a pressure-demand or other positive-pressure mode. Any self-contained breathing apparatus that has a full face piece and is operated in a pressure-demand or other positive-pressure mode.

For Unknown Concentrations or Immediately Dangerous to Life or Health – Any supplied-air respirator with full face piece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply. Any self-contained breathing apparatus with a full face piece.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical State

Solid

Appearance

Light-sensitive

Colour

White, off-white or yellow

Change in Appearance

Light

Physical Form

Crystalline powder

Odour

Faint odour

Taste

Bitter taste

Molecular Weight

171.16

Molecular Formula

C₆H₉N₃O₃

Boiling Point

Not applicable

Melting Point

320-322 F (160-161 C) with decomposition

Vapour Pressure

Not applicable

Vapor Density (air=1)

Not applicable

Specific Gravity (water=1)

Not available

pH

5.8 (saturated solution)

Volatility

Not applicable

Odour Threshold

Not available

Evaporation Rate

Not applicable

Coefficient of Water/Oil Distribution

Not available

Solvent Solubility

Soluble: dilute acids Slightly Soluble: ethanol Very Slightly Soluble: ether, chloroform, dimethylformamide

SECTION 10 - STABILITY AND REACTIVITY**Reactivity**

Stable at normal temperatures and pressure. Conditions to Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials. Incompatibilities acids, bases, oxidizing materials

Acids : Incompatible.

Bases : Incompatible.

Oxidizers (Strong) : Fire and explosion hazard. Hazardous Decomposition

Thermal decomposition products : oxides of carbon, nitrogen

Polymerization

Will not polymerize.

SECTION 11 - TOXICOLOGICAL INFORMATION**Toxicity Data**

>150 mg/kg/2 week(s) skin-rat TDLo (G.D. Searle); 40 mg/kg oral-woman TDLo; 3570 ug/kg/1 day(s) oral-man TDLo; 12 mg/kg oral-woman TDLo; 1030 mg/kg/8 week(s) oral-man TDLo; 100 mg/kg/5 day(s) intermittent Intravenous-woman TDLo; 3 gm/kg oral-rat LD50; 3800 mg/kg oral-mouse LD50; 870 mg/kg intraperitoneal-mouse LD50; 3640 mg/kg subcutaneous-mouse LD50; 34 gm/kg/34 day(s) continuous oral-rat TDLo; 6500 mg/kg/26 day(s) intermittent oral-dog TDLo

Carcinogen Status

NTP: Anticipated Human Carcinogen; IARC: Human Inadequate Evidence, Animal Sufficient Evidence, Group 2B; EC: Category 2 By oral administration, metronidazole significantly increased the incidences of lung tumors in mice of each sex, of lymphomas in female mice, and of mammary, pituitary, testicular and liver tumors in rats.

Acute Toxicity Level Moderately Toxic: ingestion Medical Conditions Aggravated by Exposure central nervous system disorders, blood system disorders, immune system disorders or allergies, liver disorders Tumorigenic Effects 219 gm/kg oral-rat TDLo/2 year(s) continuous; 181 gm/kg oral-mouse

TDLo/72 week(s) continuous; 27 gm/kg oral-rat TD/35 week(s) continuous; 8 gm/kg oral-mouse TD/14 week(s) continuous; 3 gm/kg oral-rat TD/14 week(s) continuous; 21800 mg/kg oral-mouse TD/2 year(s) intermittent; 1680 mg/kg oral-mouse TD 1-21 day(s) pregnant female continuous

Mutagenic Data

Mutation in micro-organisms - Salmonella typhimurium 25 ug/plate (+S9); mutation in microorganisms - Salmonella typhimurium 50 ug/plate (-S9); mutation in microorganisms - Escherichia coli 100 umol/L (-S9); other mutation test systems - Escherichia coli 4 mg/L; mutation in microorganisms - Escherichia coli 1 gm/L (+S9); DNA

repair - Escherichia coli 200 ug/disc; DNA adduct - Escherichia coli 2 umol;

phage inhibition capacity - Escherichia coli 500 ug/plate; DNA repair - Bacillus subtilis 200 ug/disc; mutation in microorganisms - Klebsiella pneumoniae 20 umol/L (-S9) 20 hour(s); mutation in microorganisms - other microorganisms 25 umol/L (-S9); DNA inhibition - other microorganisms 1mg/L; other mutation test systems - other microorganisms 1 mg/L; DNA inhibition - other microorganisms 5 mg/L; other mutation test systems - other microorganisms 5 mg/L; DNA inhibition - other microorganisms 5 mg/L; other mutation test systems - other microorganisms 5 mg/L; mutation in microorganisms - Neurospora crassa 8800 mg/L (-S9); body fluid assay - human Salmonella typhimurium 10 mg/kg; cytogenetic analysis - human unreported 86 mg/kg 30 day(s); cytogenetic analysis - human lymphocyte 500 mg/L; cytogenetic analysis - human oral 250 mg/kg 10 day(s)-continuous; DNA damage - rat liver 3 mmol/L; body fluid assay - rat Salmonella typhimurium 800 mg/kg; DNA damage - mouse lymphocyte 30 mmol/L 4 hour(s)-continuous; DNA damage - mouse fibroblast 300 umol/L; DNA inhibition - mouse lymphocyte 30 mmol/L 1 hour(s)-continuous; DNA inhibition - mouse other cell types 100 mg/L; body fluid assay - rat Salmonella typhimurium 100 mg/kg; cytogenetic analysis mouse oral 1200 mg/kg; host-mediated assay - mouse Salmonella typhimurium 400 mg/kg 5 day(s); host-mediated assay - mouse Escherichia coli 4 mg/kg 2 hour(s); host-mediated assay - mouse Saccharomyces cerevisiae 25 mmol/kg; DNA inhibition - hamster lung 1 mmol/L 6 day(s)-continuous; cytogenetic analysis - hamster lung 10 mmol/L; sister chromatid exchange - hamster oral 125 mg/kg; host-mediated assay - hamster embryo 200 mg/kg; DNA adduct - mammal lymphocyte 60 umol/L

Reproductive Effects

Data 16800 mg/kg oral-rat TDLo 42 day(s) male; 22400 mg/kg oral-rat TDLo 56 day(s) male; 750 mg/kg unreported-rat TDLo 30 day(s) pre pregnancy continuous; 60 mg/kg intraperitoneal-mouse TDLo 8-14 day(s) pregnant female continuous

Additional Data

May cross the placenta. May be excreted in breast milk. Interactions with drugs may occur.

HEALTH EFFECTS INHALATION

Acute Exposure

METRONIDAZOLE: No data available.

Chronic Exposure

METRONIDAZOLE: No data available.

SKIN CONTACT

Acute Exposure

METRONIDAZOLE: May cause mild dryness, transient redness, burning and irritation. Chronic Exposure

METRONIDAZOLE: No data available.

EYE CONTACT

Acute Exposure

METRONIDAZOLE: May cause redness.

Chronic Exposure

METRONIDAZOLE: No data available.

INGESTION

Acute Exposure

METRONIDAZOLE: May cause nausea, vomiting, ataxia, anorexia, malaise, and transient disorientation. No deaths or prolonged morbidity were reported from doses of 3.6 to 19.5 grams. Chronic Exposure

METRONIDAZOLE: In addition to the effects listed above, therapeutic use of metronidazole has produced diarrhea, epigastric distress, abdominal cramping, constipation, proctitis, metallic taste, furry tongue, glossitis, and stomatitis. Other effects may include dysuria, polyuria, dark colored urine, incontinence, cystitis, dyspareunia, sense of pelvic pressure, decreased libido, gynecomastia, numbness, and encephalopathy.

Jaundice and liver dysfunction are also possible. Central nervous system effects of headache, dizziness, incoordination, insomnia, irritability, depression, weakness, syncope, and convulsions may develop. Peripheral neuropathy as characterized by paresthesia of the extremities may occur and in some cases may not reverse itself.

Hypersensitive reactions of

urticaria, erythematous rash, flushing, fever, nasal congestion and dryness of the mouth (or vagina or vulva) may appear. Effects infrequently observed are reversible neutropenia, pancreatitis, pseudomembranous colitis, reversible thrombocytopenia, fleeting joint pain, and

agranulocytosis. Breast and colon cancer have occurred among individuals with crohn's

disease treated with high doses for extended periods of time. A cause and effect relationship has not been established. Significant increases in the incidences of lung tumors in mice of each sex, of lymphomas in female mice, and of mammary, pituitary, testicular and liver tumors in rats were reported. High doses produced infertility in male rats.

SECTION 12 - ECOLOGICAL INFORMATION

Ecotoxicity Data

Fish Toxicity

100000 ug/L 48 hour(s) (Mortality) Bluegill (*Lepomis macrochirus*)

Algal Toxicity

100000 ug/L NR hour(s) (Mortality) Blue-green algae
(*Anacystis nidulans*)

SECTION 13 - DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

SECTION 14 - TRANSPORT INFORMATION

Land Transport ADR/RID

No classification assigned.

Air Transport IATA/ICAO

No classification assigned.

Maritime Transport IMDG

No classification assigned.

SECTION 15 - REGULATORY INFORMATION

EC Directive 2001/58/EC

TSCA Inventory Status N

TSCA 12(b) Export

Notification Not listed.

ACUTE : N

CHRONIC : Y

FIRE : N

REACTIVE : N

SUDDEN RELEASE : N

SECTION 16 - OTHER INFORMATION**Disclaimer**

The information contained herein is based on current knowledge and experience; no responsibility is accepted that the information is sufficient or correct in all cases. Users should consider these data only as a supplement to other information gathered by them and must make independent determination of suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees, customers and third parties and the protection of the environments.

Date of Revision – 10th Dec 2010Created by: **EHS department****Unichem Laboratories Limited**

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