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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Dithranol

Dithranulom Dithranol Dithranol Dithranol 1143-38-0

N° CAS: 1143-38-0 N° EC: 214-538-0

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV

Neerlandweg 24 2610 Wilrijk Belgium

Telephone: (+32) (0)3 457 11 76
Email: info@magis-pharma.be
Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation: Belgisch Antigifcentrum Centre Antipoisons Belge

Telephone: (+32) (0)70 245 245 (Service 24/7)

Web page: www.antigifcentrum.be www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

 Skin Irrit. 2
 H315

 Eye Irrit. 2
 H319

 STOT SE 3
 H335

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H315 Causes skin irritation.

H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

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Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses,

if present and easy to do. Continue rinsing.

P312 Call a POISON CENTER/doctor if you feel unwell.

P321 Specific treatment (see on this label).

P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.

P362 Take off contaminated clothing.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

P501 Dispose of contents/container in accordance with federal, state and local

environmental control regulations.

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Dithranol

IUPAC name: 1,8-Dihydroxyanthracen-9(10H)-one

Synonyms: Anthralin

1,8-Dihydroxyanthrone

N° CAS: 1143-38-0
N° EC: 214-538-0
Molecular Formula: $C_{14}H_{10}O_3$

Content: 98.5 per cent to 101.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Consult a doctor in case of complaints. Take off all contaminated clothing.

After inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If

breathing, is difficult, give oxygen. Get medical attention.

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After skin contact: In case of contact, immediately flush skin with plenty of water. Cover the irritated

skin with an emollient. Remove contaminated clothing and shoes.

Serious skin contact: Wash with disinfectant soap and cover the contaminated skin

with an anti-bacterial cream. Seek medical attention.

After eye contact: Check for and remove any contact lenses. In case of contact, immediately flush eyes

with plenty of water for at least 15 minutes. Cold water may be used. WARM water

MUST be used. Get medical attention.

After ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give

anything by mouth to an unconscious person. Loosen tight clothing such as a collar,

tie, belt or waistband. Get medical attention if symptoms appear.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Carbon dioxide, fire-extinguishing powder or water spray. Fight

larger fire with water spray or alcohol resistant foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Flammability of the product: May be combustible at high temperature.

Flash points: Closed cup higher than 93/3 °C (200 °F).

Special remarks on explosion hazards: Dust may form explosive mixture in air.

5.3 Advice for firefighters

Surrounding fires: Small fire: Use dry chemical powder.

Large fire: Use water spray, fog or foam. Do not use water jet.

Protection against fire: Not available.

Hazardous combustion products: Carbon oxides (CO, CO₂).

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Not available.

For emergency responders

Not available.

6.2 Environmental precautions

Not available.

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6.3 Methods and material for containment and cleaning up

Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements. Large spill: Use a shovel to put material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Keep locked up. Keep away from heat. Keep away from sources of

ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Do not ingest. Do not breathe dust. Avoid

contact with skin and eyes.

Personal protection: Wear suitable protective clothing. In case of insufficient ventilation,

wear suitable respiratory equipment. If ingested, seek medical

attention.

Technical protective measures: Ground all equipment containing material.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any

incompatibilities:

Keep container tightly closed, in cool ventilated area.

Storage – away from: Protected from light. Keep away from heat. Keep away from sources

of ignition.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures

Eye/face protection: Splash goggles.

In case of a large spill: Splash goggles.

Skin protection: Lab coat

In case of large spill: Full suit. Boots.

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Hand protection: Gloves.

In case of a large spill: Gloves.

Respiratory protection: Dust respirator. Be sure to use an approved/certified respirator or equivalent.

> In case of a large spill: a self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient;

consult a specialist before handling this product.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Yellow or brownish-yellow, crystalline powder.

Odour: Odourless.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: 178 °C to 182 °C

Initial boiling point: Not available.

Boiling range: Not available.

Not available. Flash point:

Evaporation rate: Not available.

Not available. Flammability (solid/gas):

Upper/lower flammability or Not available.

explosive limits: Vapour pressure:

Not available. Vapour density:

Not available. Relative density:

Solubility: Soluble in methylene chloride, sparingly soluble in acetone, slightly soluble in EtOH

(96 per cent). It dissolves in dilute solutions of alkali hydroxides.

Solubility in water: Practically insoluble in water.

Partition coefficient Not available.

(n-octanol/water):

Not available.

Not available.

Auto-ignition temperature: Decomposition temperature: Not available. Not available. Viscosity:

Explosive properties: Not available. Not available. Oxidising properties:

9.2 Other information

Molecular weight: 226.2 g/mole

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

The product is stable.

10.3 Possibility of hazardous reactions

Polymerisation will not occur.

10.4 Conditions to avoid

Excessive heat, dust generation.

10.5 Incompatible materials

Reactive with oxidizing agents.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral LD₅₀ (mouse): > 1542 mg/kg

Skin corrosion/irritation: Causes skin irritation. Hazardous in case of skin contact (irritant).

Serious eye damage/irritation: Causes eye irritation.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast.

May affect genetic material (mutagenic) based on animal data.

Classified + (Possible) by OSHA. Classified 2B (Possible for human) by IARC. Classified Carcinogenicity:

2 (Some evidence) by NTP.

May cause cancer (tumorigenic) based on animal data.

Reproductive toxicity: Summary of evaluation of the

Not available. Not available.

CMR properties:

STOT-single exposure: Not available. STOT-repeated exposure: Not available. Aspiration Hazard: Not available.

Other: Special remarks on other toxic effects on humans

> May affect behavior and sense organs and respiration. May cause cancer in humans (tumors of gastrointestinal tract, lives) based on animal data. The toxicological

properties of this substance have not been fully investigated.

11.2 Additional information on potential adverse human health effects and symptoms

Eve contact: Causes eve irritation.

Skin contact: Causes skin irritation. Hazardous in case of skin contact (irritant).

Inhalation: May cause respiratory tract irritation. Hazardous in case of inhalation (lung irritant).

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Ingestion: May cause irritation of the digestive tract. Hazardous in case of ingestion.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Product of biodegratation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of products of biodegradation: The product itself and it products of degradation are not toxic.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air):

Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

ADR/ RID(Land), IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

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14.5 Environmental hazards

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.6 Special precautions for user

Not applicable.

IATA "Not Regulated".

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

DOT Classification: Not a DOT controlled material.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

×

Risk phrases: R36/37/38 Irritating to eyes, respiratory system and skin.

Safety phrases: S1 Keep locked up.

S7/9 Keep container tightly closed and in a well-ventilated place.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek

medical advice.

S28 After contact with skin, wash immediately with plenty of water.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S45 In case of accident or if you feel unwell seek medical advice immediately

(show the label where possible). S51 Use only in well-ventilated areas.

S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR: European Agreement concerning the International Carriage of Dangerous Goods by

Road

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

EC (number): European Community (number)

IATA: International Air Transport Association
ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods

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IUPAC: International Union of Pure and Applied Chemistry

PBT: Persistent, Bioaccumulative and Toxic substance

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

STOT: Specific Target Organ Toxicity

UN (number): United Nations (number)

vPvB: very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.

https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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