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

1.1 Product identifier

Product name: Iron(III) oxide red

Ferri oxydum rubrum Ijzer(III)oxide rood Oxyde de fer(III) rouge Eisen(III)-oxid rot

N° CAS: 1309-37-1 N° EC: 215-168-2

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: FAC SECUNDUM ARTEM NV

Oostmalsebaan 1c (unit 5)

2960 Sint-Lenaarts

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

The substance is not classified in accordance with Regulation (EU) 2015/830.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable.
Signal word(s): Not applicable.
Hazard statements: Not applicable.

Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water or shower.

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

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

if present and easy to do. Continue rinsing.

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

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Iron(III) oxide red
IUPAC name: Iron(III) oxide
Synonyms: Diiron trioxide
Ferric oxide

N° CAS: 1309-37-1 N° EC: 215-168-2 Molecular Formula: Fe_2O_3

Content: Ferric Oxide contains NLT 97.0% and NMT 100.5% of ferric oxide (Fe₂O₃), calculated

on the ignited basis.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Consult a doctor. Show safety data sheet to doctor on duty.

After inhalation: Remove to fresh air. If breathing is irregular, call a doctor immediately. Only give

artificial respiration if breathing stops or under medical supervision.

After skin contact: Wash immediately with plenty of soap and water for at least 15 minutes. Remove all

contaminated clothing immediately. Get medical attention if irritation develops and

persists.

After eye contact: Remove contact lenses and rinse immediately with plenty of water, including under

eyelids, for at least 15 minutes. Get medical attention.

After ingestion: If conscious, give victim plenty of water to drink. Never give anything by mouth to

an unconscious person. Call a doctor immediately. a doctor immediately.

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.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water mist.

Nearby fires (containers exposed to fire): Water spray or water fog.

Unsuitable extinguishing media: Direct water jet.

5.2 Special hazards arising from the substance/mixture

Non-combustible. Possibility of formation of hazardous vapours by fire in the surroundings. Fire may cause fumes of phosphorus oxides.

5.3 Advice for firefighters

Cool containers with water to prevent decomposition of product Surrounding fires:

and development of health hazards. Always use full fire protection.

Collect water from entering sewage system. Dispose of

contaminated fire extinguishing water and residues in accordance

with applicable regulations.

Helmet with visor, fireproof clothing (jacket and trousers with straps Protection against fire:

> around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the entire face of the operator or self (self protective) in the case of large quantities of

smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid inhalation of dust. Evacuate the danger area, follow emergency procedures, consult experts.

For emergency responders

Not available.

6.2 Environmental precautions

Avoid penetration of products into sewers, surface water, ground water.

6.3 Methods and material for containment and cleaning up

Soak up with earth or inert material. Collect most of the material and remove the residue with water jets, follow recommendations in section 13.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid dispersal of the product in the environment. Smoking, eating Precautions for safe handling:

> and drinking must be prohibited in the application area. Keep the product in containers made of material identical to the original one.

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The product does not require special storage measures. Store

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Personal protection: Not available.

Technical protective measures: Not available.

Handling: Comply with occupational health and safety legislation.

7.2 Conditions for safe storage, including any incompatibilities

Storage: In a well-closed container.

Conditions for safe storage, including any

incompatibilities:

containers in a cool, dry place.

Storage – away from: Not available.

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

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if it is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a visco-elastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection: Not required.

Skin protection: Not required.

Hand protection: Not required.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust

mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or

CEN (EU).

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: Red powder.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

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Melting/freezing point: 1538°C

Initial boiling point: Not available. Boiling range: Not available. Flash point: Not available. Evaporation rate: Not available. Flammability (solid/gas): Not available. Upper/lower flammability or Not available.

explosive limits:

Not available.

Vapour pressure: Not available. Vapour density: Relative density: Not available. Solubility: Not available. Solubility in water: Not available.

Partition coefficient

Not available.

(n-octanol/water):

Auto-ignition temperature: Not available. Decomposition temperature: Not available. Viscosity: Not available. Explosive properties: Not available. Oxidising properties: Not available.

9.2 Other information

Molecular weight: 159.69 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Acute oral toxicity (LD₅₀, rat): > 10000 mg/kg

Skin corrosion/irritation: Not available. Serious eye damage/irritation: Not available. Not available. Respiratory/skin sensitisation: Germ cell mutagenicity: Not available.

The IARC working group evaluated the biological effects of talc and concluded, due Carcinogenicity:

to in vivo and in vitro studies, that there is insufficient evidence of carcinogenicity or

genetic toxicity in both animal and human experiments.

Reproductive toxicity: Not available. Summary of evaluation of the

Not available.

CMR properties:

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

There are no known health related events due to exposure to the product. In any Other:

case, it is recommended to comply with the rules of good industrial hygiene.

11.2 Additional information on potential adverse human health effects and symptoms

Not available. Eye contact: Skin contact: Not available. Inhalation: Not available. Ingestion: Not available. Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

According to available data, the product does not contain PBT or vPvB substances in concentrations above 0.10 %.

12.6 Other adverse effects

Use in accordance with good laboratory practice, avoid dispersal into the environment. Inform the competent authorities if the product contaminates ground water, sewage, soil or vegetation.

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SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container

Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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

It is not dangerous in transport.

IATA/ICAO (Air):

14.2 UN proper shipping name

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

It is not dangerous in transport.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

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

It is not dangerous in transport.

IATA/ICAO (Air):

14.4 Packing group

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

It is not dangerous in transport.

IATA/ICAO (Air):

14.5 Environmental hazards

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

It is not dangerous in transport.

IATA/ICAO (Air):

14.6 Special precautions for user

It is not dangerous in transport.

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

Not available.

14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable. Risk phrases: Not applicable.

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

medical advice.

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S27/28 After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of soap and water.

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

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

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
 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 info@magis-pharma.be