

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

RIFAMPICINUM

EN

FORM-06-14-01 (V00)

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Version: 00



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

1.1 Product identifier

Product name: Rifampicin
Rifampicinum
Rifampicine
Rifampicine
Rifampicin

N° CAS: 13292-46-1

N° EC: 236-312-0

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: 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

Acute Tox. 4	H302
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:

H302	Harmful if swallowed.
H315	Causes skin irritation.

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H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
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).
P330	Rinse mouth.
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 to...
Additional applicable label elements:	

2.3 Other hazards

Other hazards not contributing to the classification: Exposure may produce an allergic reaction.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Rifampicin
IUPAC name:	3-(((4-Methyl-1-piperazinyl)imino)-methyl)-rifamycin
Synonyms:	Archidyn; Arficin; Dione-21-Acetate; Rifadine; Tubocin
N° CAS:	13292-46-1
N° EC:	236-312-0
Molecular Formula:	C ₄₃ H ₅₈ N ₄ O ₁₂
Content:	97.0 per cent to 102.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Move to fresh air in case of accidental inhalation. Assure fresh air breathing.
After skin contact:	Rinse skin with water/shower.
After eye contact:	Rinse with water while holding the eyes wide open. Contact lenses should be removed.
After ingestion:	Rinse mouth out with water.

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

In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Use extinguishing media appropriate for surrounding fire. Water spray. Carbon dioxide. Dry powder. Foam.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires:	Firefighting instructions: Dilute with water.
Protection against fire:	Precautionary measures fire: Use normal individual fire protective equipment.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

General measures: Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection.

For non-emergency personnel

Protective equipment: See sections 7 and 8.

For emergency responders

Not available.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Clean with water.

6.4 Reference to other sections

Not available.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Not available.
Personal protection:	Not available.
Technical protective measures:	Comply with applicable regulations.
Handling:	Handle and open container with care. See section 8. Handle in accordance with good industrial hygiene and safety procedures. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Comply with applicable regulations.
Conditions for safe storage, including any incompatibilities:	Under nitrogen in an airtight container, protected from light, at a temperature not exceeding 25 °C.
Storage – away from:	Strong oxidizing agents.

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

Not available.

Individual protection measures

Eye/face protection:	Not determined.
Skin protection:	Lab coat.
Hand protection:	Gloves.
Respiratory protection:	Quarter mask (DIN EN 140).
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:	Reddish-brown or brownish-red, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	4.5 – 6.5 (1%)

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Melting/freezing point:	183 - 188 °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 explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Soluble in methanol, slightly soluble in acetone and in ethanol (96 per cent).
Solubility in water:	Slightly soluble in water (≥ 1 mg/l).
Partition coefficient (n-octanol/water):	Log Pow: 4.24 at 20°C
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Not available.

10.3 Possibility of hazardous reactions

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

None under normal use.

10.6 Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not classified. LD ₅₀ oral (rat): 1570 mg/kg ATE (oral): 500 000 mg/kg
Skin corrosion/irritation:	Causes skin irritation. pH: 4,5 - 6,5 (1%)
Serious eye damage/irritation:	Causes serious eye irritation. pH: 4,5 - 6,5 (1%)
Respiratory/skin sensitisation:	Not classified
Germ cell mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive toxicity:	Suspected of damaging the unborn child. May cause harm to breast-fed children.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	May cause respiratory irritation.
STOT-repeated exposure:	Not classified
Aspiration Hazard:	Not classified
Other:	Potential Adverse human health effects and symptoms: Avoid any direct contact with the product. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

11.2 Additional information on potential adverse human health effects and symptoms

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

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology-general: See section 2
Ecology - water: Soluble in water.
EC₅₀ Daphnia: 3300 mg/l EC₅₀ - 48 Hour - *Daphnia magna*

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Log Pow: 4.24 at 20°C

12.4 Mobility in soil

Not available.

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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

Regional legislation (waste): Dispose in a safe manner in accordance with local/national 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) : No dangerous good in sense of transport regulations

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : Not available.

14.6 Special precautions for user

Not available.

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

Not available.

14.8 Additional transport information

N/A

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R22 Harmful if swallowed.

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

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Safety phrases:

R63 Possible risk of harm to the unborn child.

R64 May cause harm to breastfed babies.

S1 Keep locked up.

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

S20/21 When using do not eat, drink or smoke.

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

S27 Take off immediately all contaminated clothing.

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

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

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

S64 If swallowed, rinse mouth with water (only if the person is conscious).

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
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 Bioaccumulative

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.

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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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