

Material Safety Data Sheet

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

EN

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Publication: 15/09/2022

Revision: XX/XX/XXXX

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GUAIFENESINUM

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

1.1 Product identifier

Product name: Guaifenesin
Guaifenesinum
Guaifenesine
Guaifénésine
Guaifenesin

N° CAS: 93-14-1

N° EC: 202-222-5

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

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302 Harmful if swallowed.

Precautionary statements:

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P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330	Rinse mouth.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Guaifenesin
IUPAC name:	(2RS)-3-(2-Methoxyphenoxy)propane-1,2-diol
Synonyms:	Guaiacol glyceryl ether Glycerol guaiacolate
N° CAS:	93-14-1
N° EC:	202-222-5
Molecular Formula:	C ₁₀ H ₁₄ O ₄
Content:	98.0 per cent to 102.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Instantly remove any clothing soiled by the product.
After inhalation:	Take affected persons into the open air and position comfortably. In case of unconsciousness bring patient into stable side position for transport. Seek medical treatment in case of complaints.
After skin contact:	Instantly rinse with water.
After eye contact:	Rinse opened eye for several minutes under running water. Then consult doctor.
After ingestion:	Wash out mouth with water provided person is conscious. Give nothing by mouth in case of unconsciousness or convulsions. Do NOT give an unconscious person anything to drink! Seek medical treatment.

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

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Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray, fire-extinguishing powder, carbon dioxide, foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Material is combustible.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear full protective suit. Wear self-contained breathing apparatus.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear protective equipment. Keep unprotected persons away. Avoid causing dust. Ensure adequate ventilation.

For emergency responders

Wear protective equipment. Keep unprotected persons away. Avoid causing dust. Ensure adequate ventilation.

6.2 Environmental precautions

Do not allow product to reach sewage system or water bodies.

6.3 Methods and material for containment and cleaning up

Dispose of the collected material according to regulations.

Prevent formation of dust. Ensure adequate ventilation.

6.4 Reference to other sections

See section 7 for information on safe handling.

See section 8 for information on personal protective equipment.

See section 13 for information on disposal.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Keep containers tightly sealed. Prevent formation of dust.
Information about protection against explosions and fires: Protect against electrostatic charges.

Personal protection: Not available.

Technical protective measures: Ensure good ventilation/exhaustion at the workplace.

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Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Store only in the original container.

Conditions for safe storage, including any incompatibilities: Store under dry conditions. Store container in a well ventilated 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

The usual precautions for handling the chemicals must be observed. Do not eat, drink or smoke while working. Instantly remove any soiled and impregnated garments. Store protective clothing separately. Do not inhale dust/smoke/mist.

Individual protection measures

Eye/face protection: Tightly sealed safety glasses.

Skin protection: Protective work clothing.

Hand protection: Protective gloves.

Material of gloves: The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material: The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection: Breathing protection recommended.

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: White or almost white, crystalline powder.

Odour: Characteristic.

Odour threshold: Not available.

pH: Not available.

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Melting/freezing point:	78 – 82 °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 ethanol (96 per cent).
Solubility in water:	Sparingly soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Product is not explosive.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Thermal decomposition/conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Poisonous gases/vapours.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Harmful if swallowed. Oral LD50 (rat): 1 510 mg/kg
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Respiratory/skin sensitisation:	Allergic reactions and sensitisation are possible.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Harmful if swallowed.
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

Not applicable.

12.6 Other adverse effects

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General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: After prior treatment, the product must be landfilled or incinerated in accordance with regulations for the disposal of particularly hazardous waste. Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Uncleaned packaging: Recommendation: Disposal must be made according to official 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),
IATA/ICAO (Air) : Not classified.

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

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

14.6 Special precautions for user

Not applicable.

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

Not applicable.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

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Irritant

Risk phrases: R22 Harmful if swallowed.

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

15.2 Chemical safety assessment

A chemical safety assessment 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 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.

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

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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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