

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

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BELLADONNAE FOLII TINCT. NORM.

Publication: 21/04/2021

Revision: 21/04/2021

Version: 00



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

1.1 Product identifier

Product name:	Belladonna leaf tincture, standardised Belladonnae folii tinctura normata Belladonnablاد gestandaardiseerde tinctuur Teinture titrée de feuille de belladone Belladonna Blatt standardisierte Tinktur
N° CAS:	N/A
N° EC:	N/A

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	FRAVER NV Keizershoek 336 2550 Kontich 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

Flammable liquids (category 2)	H225
Eye irritation (category 2)	H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H225	Highly flammable liquid and vapour
H319	Causes serious eye irritation

Precautionary statements:

P210	Keep away from heat/sparks/open flames/hot surfaces – No smoking
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Additional applicable label elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Ethanol preparation of *Atropa belladonna* L.

Product name: Ethanol

IUPAC name: Ethanol

Synonyms: Ethyl alcohol

Alcohol

N° CAS: 64-17-5

N° EC: 200-578-6

Molecular Formula: C_2H_6O

Content: 64% (V/V) to 69% (V/V) ethanol

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: Provide fresh air. Consult a doctor when feeling unwell.

After skin contact: Wash off with plenty of water.

After eye contact: Rinse out with plenty of water, keeping the eyes wide open. Consult an ophthalmologist.

After ingestion: Make the victim drink plenty of water when conscious. Consult a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Irritant effects, euphoria, dizziness, inebriation, narcosis, respiratory paralysis.

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: CO_2 , water, foam, powder.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Combustible material. Development of hazardous combustion gases and vapours possible in the event of fire

5.3 Advice for firefighters

Surrounding fires: Remove container from danger zone and cool with water.

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Protection against fire:

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

Do not breathe vapors/aerosols. Wear protective clothing.

For emergency responders

Do not breathe vapors/aerosols. Wear protective clothing.

6.2 Environmental precautions

Do not empty into drains. Risk of explosion.

6.3 Methods and material for containment and cleaning up

Take up with liquid-absorbent material. Forward for disposal. Clean up affected area.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Observe label precautions.

Personal protection:

Use protective clothing when handling the product.

Technical protective measures:

Not available.

Handling:

Observe label precautions.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Tightly closed at a cool dark and dry place.

Conditions for safe storage, including any incompatibilities:

Not available.

Storage – away from:

Keep container 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

Ethanol: Derived No Effect Level (DNEL):

Worker DNEL, acute	Local effects	Inhalation	1900 mg/m ³
Worker DNEL, longterm	Systemic effects	Dermal	343 mg/kg Body weight
Worker DNEL, longterm	Systemic effects	Inhalation	950 mg/m ³
Consumer DNEL, acute	Local effects	Inhalation	950 mg/m ³
Consumer DNEL, longterm	Systemic effects	Dermal	206 mg/kg Body weight

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Consumer DNEL, longterm	Systemic effects	Inhalation	114 mg/m ³
Consumer DNEL, longterm	Systemic effects	Oral	87 mg/kg Body weight
Ethanol: Predicted No Effect Concentration (PNEC):			
PNEC Fresh water	0,96 mg/L		
PNEC Marine water	0,79 mg/L		
PNEC Fresh water sediment	3,6 mg/kg		
PNEC Soil	0,63 mg/kg		
PNEC Aquatic intermittent release	2,75 mg/L		
PNEC Sewage treatment plant	580 mg/L		
PNEC oral	720 mg/kg		

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection: Required (EN 166)

Skin protection: Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

Hand protection: Full contact: Glove material: butyl rubber; Layer thickness: 0,7 mm; Breakthrough time: > 480 min
Splash contact: Glove material: nitrile rubber; Layer thickness: 0,4 mm; Breakthrough time: > 120 min

Respiratory protection: Required when dusts are generated Filter A-(P2) (EN 141)

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:	Green liquid
Odour:	Aromatic
Odour threshold:	Not available.
pH:	About 6
Melting/freezing point:	Not available.
Initial boiling point:	84°C
Boiling range:	Not available.
Flash point:	27,0°C
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.

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Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	0,850 – 0,950
Solubility:	Not available.
Solubility in water:	Completely miscible
Partition coefficient (n-octanol/water):	< 1
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

Vapours may form explosive mixture with air.

10.2 Chemical stability

Stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Risk of ignition or formation of inflammable gases or vapours with: Alkali metals, alkali oxides, anhydrides, strong oxidizing agents.

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

Various plastics, rubber.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	LD50 oral (rat): 6200 mg/kg LD50 dermal (rabbit): > 20000 mg/kg LC50 inhalation (rat): > 8000 mg/L/4h
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Slight irritations.

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Respiratory/skin sensitisation:	Slight mucosal irritations. Risk of absorption.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Eye irritation.
Skin contact:	Not available.
Inhalation:	Mucosal irritation, dizziness, inebriation, narcosis, respiratory paralysis.
Ingestion:	Neasea and vomiting. Euphoria
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Biodegradability Ethanol 94% OECD 301E

12.3 Bioaccumulative potential

Bioaccumulation is not expected ($\log P$ (o/w) < 1)

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

PBT- / vPvB assessment not available as chemical safety assessment is not required.

12.6 Other adverse effects

No ecological problems are to be expected when the product is handled and used with due care and attention.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Contact a licensed professional waste disposal service to dispose of this material. Observe all federal, state and local environmental regulations.

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SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), UN 1197
IATA/ICAO (Air) :

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 3
IATA/ICAO (Air) :

14.4 Packing group

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

14.5 Environmental hazards

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

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

Not available.

SECTION 15: REGULATORY INFORMATION

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

N/A

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

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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

Classification based on ethanol.

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

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