

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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AURANTII AMARI EPICARPII ET MESOCARPII TINCTURA

Publication: 05/03/2022

Revision: 22/08/2023

Version: 01



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

1.1 Product identifier

Product name:	Tintura aurantii amari Aurantii amari epicarpium et mesocarpium tinctura Bittere oranje epicar en mesocarp tinctuur Teinture d'épicarpe et de mésocarpe d'orange amère Tintura auratii
N° CAS:	72968-50-4
N° EC:	277-143-2

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:	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

Highly flammable liquid and vapour.	H225
Causes serious eye irritation.	H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

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Hazard pictogram(s):



Signal word(s):

DANGER

GEVAAR

Hazard statements:

H225

Highly flammable liquid and vapour.

H319

Causes serious eye irritation.

Precautionary statements:

P210

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.
No smoking.

Additional applicable label
elements:

Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Tintura aurantii amari
IUPAC name:	4R)-1-methyl-4-(prop-1-en-2-yl)cyclohex-1-ene
Synonyms:	Tintura aurantii Tincture of orange peel
N° CAS:	72968-50-4
N° EC:	277-143-2 ^[1] _{SEP}
Molecular Formula:	C ₁₀ H ₁₆
Content:	5.0

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Notify the doctor. Show the doctor the security file of this service.
[After inhalation:	Go outside (open air) If breathing is irregular, call a doctor immediately. Only apply artificial respiration if respiration is stopped or under medical supervision.

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After skin contact:

Wash immediately with 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, clean under the eyelids, for at least minus 15 minutes. Get medical attention if needed.

After ingestion:

Not available

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:

Foam, dry powder, carbon dioxide, sand, water mist.

Unsuitable extinguishing media:

Waterjet stream.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires:

Cool containers with water to prevent the decomposition of the product and the development of potential health hazards. Always use full fire protection.

Protection against fire:

Collect water that should not enter the sewer. Eliminate the contaminated water used for extinguishing and the remains of the second the current regulation.

Helmet with visor, fireproof clothing (jacket and trousers with straps around the arms, legs and waist, ES 469), gloves (fireproof and dielectric, EN 659), a face mask covering the entire face of the operator or car (self-protective) in the case of large amounts of smoke, a self-contained breathing apparatus (EN 137)

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

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6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

For control of self-protection check section 8.

For emergency responders

Avoid the formation of dust. Avoid breathing vapors, mist or gas. Ensure proper ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

6.2 Environmental precautions

Prevent further leakage or spillage if it can be done safely. Do not allow the product to enter the sewer system.

6.3 Methods and material for containment and cleaning up

Clean and shovel. Store in appropriate, closed containers for disposal.

6.4 Reference to other sections

For exposition control and self-protection, check section 8.

For the disposal of waste, follow the recommendations of section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Do not smoke, drink or eat in the working area.
Personal protection:	For control of self-protection check section 8.
Technical protective measures:	Not available.
Handling:	Protect the product from light.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Keep in the original container.
Conditions for safe storage, including any incompatibilities:	Store closed containers in a well-ventilated area away from direct sunlight.
Storage – away from:	Keep containers away from incompatible materials, check section 10.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Under all the circumstances it must always use the right technical measures and self-protection. Ensure good ventilation at the workplace through effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE mark attesting to compliance with the applicable regulations. Arrange an emergency shower with a visco-elastic tray.

8.2 Exposure controls

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Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection: Safety glasses and mask according to the regulation EN166.

Skin protection: Choose body protection according to the quantity and concentration of the hazardous substance in the workplace. Use the correct precautions of industrial hygiene, respect the security laws.

Hand protection: Wash your hands before breaks and after finishing working. Gloves should be according to the regulation EU 89/686/CEE and EN374.

Respiratory protection: Where risk assessment shows air purifying respirators to be appropriate, use type N95 (USA) or type P1(EN 143) dust mask. Use respirators and components tested and approved under appropriate government standards such as NIOSH (USA) or CEN (EU).

Not available.

Thermal hazards:

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Not available.

Odour: Not available.

Odour threshold: Not available.

pH: 5.0

Melting/freezing point: Not available.

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: 0.927g/mL

Solubility: Not available.

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Solubility in water:	Not available.
Partition coefficient (n-octanol/water):	Not available.
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

Not available.

10.2 Chemical stability

Not available.

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.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

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

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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: Not available.

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

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Contaminated packaging. Dispose of as an unused product.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), UN1197
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), No
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

Hazard symbol:



DANGER
GEVAAR

Risk phrases:

R00

Safety phrases:

Protected from light.

15.2 Chemical safety assessment

Not available.

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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 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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the [FSA]

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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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