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

1.1 Product identifier

Product name: Orange flavour

Orange flavor Sinaasappelaroma Arôme Orange

Orangen-Geschmack

N° CAS: Not available.
N° EC: Not available.

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: Magis-Pharma NV

Neerlandweg 24 2610 Wilrijk 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

Aquatic Chronic 3 H412

2.2 Label elements

Labelling according to (EC) n° 1272/2008

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

Hazard statements:

H412 Harmful to aquatic life with long lasting effects.

EUH208 Contains Linalool min. 96% FCC (78-70-6), Orange oil 7-fold (8028-46-6). May

produce an allergic reaction.

Precautionary statements: Not applicable.

Additional applicable label Not applicable.

elements:

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2.3 Other hazards

This substance/mixture does not meet the PBT criteria of the REACH Regulation, annex XIII. This substance/mixture does not meet the vPvB criteria of the REACH Regulation, annex XIII.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Product name: Orange oil 7-fold

IUPAC name: Orange oil

Synonyms: Orange, sweet, ext.

 N° CAS: 8028-46-6 N° EC: 232-433-8 Molecular Formula: Not available. Content: 0.1 – 1%

Product name: Linalool min. 96% FCC

IUPAC name: 3,7-dimethylocta-1,6-dien-3-ol

Synonyms: Ho wood oil

Linalyl alcohol

 N° CAS: 78-70-6 N° EC: 201-134-4 Molecular Formula: $C_{10}H_{18}O$ Content: 0.1-1%

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Never administer anything by mouth to an unconscious person. If you feel unwell,

call a doctor (show them this label if possible).

After inhalation: Allow the affected person to breathe fresh air. Let the victim rest.

After skin contact: Remove contaminated clothing, wash exposed skin with mild soap and water, then

rinse with warm water.

After eye contact: Rinse immediately and profusely with water. Seek medical attention if pain or

redness persists.

After ingestion: Rinse mouth. Do not induce vomiting. Urgently consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

Not expected to present a significant hazard under normal conditions of use.

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. Atomized water. Sand.

Unsuitable extinguishing media: Do not use a strong water jet.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires: Cool the exposed vessels with a water spray or mist. Use extreme

caution when fighting a chemical fire. Avoid releasing the

extinguishing water into the environment.

Protection against fire: Do not enter fire zone without suitable safety equipment, including

respiratory protection.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Making redundant staff go away.

For emergency responders

Equip cleaning personnel with appropriate protection.

Ventilate the area.

6.2 Environmental precautions

Do not allow to enter sewers or public waters. Notify appropriate authorities if liquid enters sewers or public waters. Avoid release into the environment.

6.3 Methods and material for containment and cleaning up

Soak up the spilled product as soon as possible with inert solids such as clay or silica. Clean up leaked/spilled dust. Keep separate from other material.

6.4 Reference to other sections

See Section 8. "Exposure controls and personal protection".

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Do not breathe vapors. Avoid contact with skin, eyes or clothing.

Keep away from sources of ignition - No smoking. Ensure proper ventilation of the work area. Wash hands and other exposed areas with mild soap and water before eating, drinking, smoking or leaving

work.

Personal protection: Not available.

Technical protective measures: Ensure proper ventilation of the work area

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Hygiene measures: Remove and wash contaminated clothing immediately before reuse. After working with this product, wash

skin and hands thoroughly. Do not eat, drink or smoke while using

Store only in the original container in a cool, well-ventilated place.

this product.

7.2 Conditions for safe storage, including any incompatibilities

Storage: In a well-closed container.

Conditions for safe storage, including any

incompatibilities:

Non-combining substances: Strong bases. Strong acids.
Incompatible materials: Ignition sources. Direct sunlight.

Storage – away from: Protected from light. Keep away from sources of ignition.

7.3 Specific end use(s)

Handling:

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

Avoid unnecessary exposure.

Eye/face protection: Not determined.

Skin protection: Not determined.

Hand protection: Not determined.

Respiratory protection: Wear an appropriate mask.

Thermal hazards: Not determined.

Environmental exposure control

Do not eat, drink or smoke while using.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Diffuse, colorless to pale yellow liquid.

Odour: Characteristic.
Odour threshold: Not available.

pH: 6-8

Melting/freezing point: Not available. Initial boiling point: 138.9 °C
Boiling range: Not available.

Flash point: 87 °C

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Evaporation rate: Not available. Flammability (solid/gas): Non-flammable.

Upper/lower flammability or

Not available.

explosive limits:

Vapour pressure: Not available.
Vapour density: Not available.

Relative density:

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

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Not established.

10.3 Possibility of hazardous reactions

Not established.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Vapour. Carbon monoxide. Carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not classified. Skin corrosion/irritation: Not classified.

pH: 6 - 8

Based on available data; classification criteria not met.

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Serious eye damage/irritation: Not classified.

8 - 6 : Hq

Based on available data; classification criteria not met.

Respiratory/skin sensitisation: Not classified.

Based on available data; classification criteria not met.

Germ cell mutagenicity: Not classified.

Based on available data; classification criteria not met.

Carcinogenicity: Not classified.

Based on available data; classification criteria not met.

Not classified. Reproductive toxicity:

Based on available data; classification criteria not met.

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: Not classified.

Based on available data; classification criteria not met.

STOT-repeated exposure: Not classified.

Based on available data; classification criteria not met.

Aspiration Hazard: Not classified.

Based on available data; classification criteria 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: Not available. Not available. Aspiration:

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology - water: Harmful to aquatic organisms, with long lasting effects.

Acute aquatic toxicity: Not classified. Chronic aquatic toxicity: Harmful to aquatic organisms, with long lasting effects.

12.2 Persistence and degradability

May cause long-term adverse effects in the environment.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

This substance/mixture does not meet the PBT criteria of the REACH Regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of the REACH Regulation, annex XIII.

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12.6 Other adverse effects

Additional Information: Prevent discharge into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendations for disposal of products/packaging: Dispose of in a safe manner in accordance with local/national regulations.

Ecology - waste materials: Prevent discharge into the environment.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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

Not applicable.

IATA/ICAO (Air):

14.2 UN proper shipping name

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

Not applicable.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

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

Not applicable.

IATA/ICAO (Air):

14.4 Packing group

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

Not applicable.

IATA/ICAO (Air):

14.5 Environmental hazards

Environmental hazard: No ADR/RID(Land),IMDG(Sea), IATA/ICAO (Air): Marine pollution: No

14.6 Special precautions for user

Not available.

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: Not applicable.

Risk phrases: R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the

aquatic environment.

Safety phrases: Not applicable.

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15.2 Chemical safety assessment

No chemical safety assessment has 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 GoodsIUPAC: International Union of Pure and Applied ChemistryPBT: 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

Classification based on the main component.

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 FRAVER NV info@magis-pharma.be