

Bitter-orange epicarp and mesocarp tincture

Safety Data Sheet

900300

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Issue date: 13/09/2011 Revision date 04/06/2018
Supersedes 13/03/2017

Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product name : Bitter-orange epicarp and mesocarp tincture
Product code : 900300
Product group : Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - The Netherlands
T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] (Mixtures): SDS < 2015
Show CLP information & DPD classification in section 2.1

Flammable liquids, Category 3 H226

Full text of H statements : see section 16

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

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Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display extra hazard information, see display

Hazard pictograms (CLP) :



GHS02

Signal word (CLP) : Warning

Hazard statements (CLP) : H226 - Flammable liquid and vapour.

Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, open flames, sparks. No smoking.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethanol 96% V/V	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	63 - 66.5	F; R11	Flam. Liq. 2, H225
Purified water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	27 - 28.5	Not classified	Not classified
Bitter-orange epicarp and mesocarp	(CAS-No.) 72968-50-4 (EC-No.) 277-143-2		Not classified	Not classified

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

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First-aid measures after inhalation : Allow affected person to breathe fresh air.

First-aid measures after skin contact : Rinse with plenty of water.

First-aid measures after eye contact : Immediately rinse with plenty of water.

First-aid measures after ingestion : Drink plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after ingestion : Sleepiness. Vomiting. Headache. Narcosis.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable extinguishing media : Dry powder
Foam
Carbon dioxide.

Unsuitable extinguishing media : Water.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Vapours are heavier than air and may spread along floors. On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide.

Explosion hazard : Without adequate ventilation formation of explosive mixtures may be possible.

5.3. Advice for firefighters

Firefighting instructions : Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers.

Protection during firefighting : Wear proper protective equipment.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****6.1.1. For non-emergency personnel**

Emergency procedures : Ensure adequate air ventilation.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Stop leak if safe to do so. Small quantities of liquid spill: take up in non-combustible absorbent material and shovel into container for disposal. To clean the floor or objects contaminated by this product, use : Water.

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6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharges.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store away from heat.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Bitter-orange epicarp and mesocarp tincture	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	1900 mg/m ³
Long-term - systemic effects, dermal	343 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	950 mg/m ³
DNEL/DMEL (General population)	
Acute - local effects, inhalation	950 mg/m ³
Long-term - systemic effects, oral	87 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	114 mg/m ³
Long-term - systemic effects, dermal	206 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.96 mg/l
PNEC aqua (marine water)	0.79 mg/l
PNEC aqua (intermittent, freshwater)	2.75 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	3.6 mg/kg dwt
PNEC sediment (marine water)	2.9 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.63 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	0.72 g/kg food
PNEC (STP)	
PNEC sewage treatment plant	580 mg/l

8.2. Exposure controls

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

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Respiratory protection:

In case of inadequate ventilation wear respiratory protection. Dustmask with filtertype P1

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Liquid
Colour	: brown.
Odour	: Characteristic.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: 23 - 35 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 0.952 - 1.103 g/cm ³ 20°C
Solubility	: Soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

acids

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Alkali metals.
Strong oxidizers.

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Bitter-orange epicarp and mesocarp tincture	
LD50 oral rat	15010 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 14450 - 15560

Ethanol 96% V/V (64-17-5)	
LD50 oral rat	15010 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 14450 - 15560
LD50 oral	8300 mg/kg bodyweight Animal: mouse

Skin corrosion/irritation : Not classified
 Serious eye damage/irritation : Not classified
 Respiratory or skin sensitisation : Not classified
 Germ cell mutagenicity : Not classified
 Carcinogenicity : Not classified

 Reproductive toxicity : Not classified
 STOT-single exposure : Not classified
 STOT-repeated exposure : Not classified

Bitter-orange epicarp and mesocarp tincture	
NOAEL (subchronic, oral, animal/male, 90 days)	< 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
NOAEL (subchronic, oral, animal/female, 90 days)	> 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)

Ethanol 96% V/V (64-17-5)	
NOAEL (subchronic, oral, animal/male, 90 days)	< 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
NOAEL (subchronic, oral, animal/female, 90 days)	> 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

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Ethanol 96% V/V (64-17-5)	
LC50 fish 1	14.2 g/l Test organisms (species): Pimephales promelas
LC50 fish 2	13000 mg/l 96h (Oncorhynchus mykiss, OECD 203)
LC50 other aquatic organisms 1	275 mg/l 72h (Chlorella vulgaris, OECD 201)
EC50 Daphnia 1	12340 mg/l 48 h.
NOEC (chronic)	9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d'
EC10	12 mg/l/72h (Chlorella vulgaris, OECD 201)
bacteria (Pseudomonas putida)	toxic limit concentration: 6500 mg/l
Activated sludge	Damage from 15 g / l
Behaviour in sewage treatment plants	EC50 > 1000 mg/l

12.2. Persistence and degradability

Ethanol 96% V/V (64-17-5)	
Persistence and degradability	readily degradable in water.
Biochemical oxygen demand (BOD)	0.93 - 1.67 g O ₂ /g substance
Chemical oxygen demand (COD)	1.99 g O ₂ /g substance
ThOD	2.1 g O ₂ /g substance
BOD (% of ThOD)	90 % ThOD

12.3. Bioaccumulative potential

Ethanol 96% V/V (64-17-5)	
Log Pow	- 0.31
Bioaccumulative potential	Slightly or not bioaccumulative.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal : Dispose in a safe manner in accordance with recommendations local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IATA

ADR	IATA
14.1. UN number	
1293	1293

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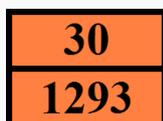
according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

ADR	IATA
14.2. UN proper shipping name	
TINCTURES, MEDICINAL	Tinctures, medicinal
14.3. Transport hazard class(es)	
3	3
	
14.4. Packing group	
III	III
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

- Overland transport

Classification code (ADR) : F1
Special provisions (ADR) : 601
Limited quantities (ADR) : 51
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P001, IBC03, LP01, R001
Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions (ADR) : T2
Portable tank and bulk container special provisions (ADR) : TP1
Tank code (ADR) : LGBF
Vehicle for tank carriage : FL
Transport category (ADR) : 3
Special provisions for carriage - Packages (ADR) : V12
Special provisions for carriage - Operation (ADR) : S2
Hazard identification number (Kemler No.) : 30
Orange plates :



Tunnel restriction code (ADR) : D/E
EAC code : •2YE

- Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y344
PCA limited quantity max net quantity (IATA) : 10L

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PCA packing instructions : 355
(IATA)
PCA max net quantity (IATA) : 60L
CAO packing instructions : 366
(IATA)
CAO max net quantity (IATA) : 220L
Special provisions (IATA) : A3
ERG code (IATA) : 3L

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

14	Proper Shipping Name (IATA)	Modified	Corrected missing information in IATA part of section 14
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Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

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Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of R-, H- and EUH-statements:

Flam. Liq. 2	Flammable liquids, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.

SDS EU (REACH Annex II) duchefa nieuwe logo

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.