

Trade name: Chamomillae oleum coctum

Substance number: 263241 Version: 3 / CH Date revised: 31.03.2025

Replaces Version: 2 / CH Print date: 31.03.25

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

# 1.1. Product identifier

Chamomillae oleum coctum

Item No. 26324100

# Substance / product identification

REACH Registry No. EXCEMPT

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

## Use of the substance/preparation

Manufacture of pharmacutical products, Active pharmacutical substance

# 1.3. Details of the supplier of the safety data sheet

#### Address/Manufacturer

Hänseler AG

Industriestrasse 35

9100 Herisau

Telephone no.

0041 (0)71 353 58 58 sdb@haenseler.ch

E-mail address of

person responsible for this SDS

## 1.4. Emergency telephone number

Switzerland: 145 / Abroad +41 (0)44 251 51 51

# **SECTION 2: Hazards identification \*\*\***

#### 2.1. Classification of the substance or mixture

Voluntary product information following the Safety Data Sheet format

This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

## 2.2. Label elements

## Labelling according to regulation (EC) No 1272/2008

The product does not require a hazard warning label in accordance with Regulation (EC) No 1272/2008.

## 2.3. Other hazards

No special hazards have to be mentioned.

The Substance does not meet PBT-criteria. This substance does not meet the vPvB-criteria. This substance does not have endocrine disrupting properties with respect to humans. This substance does not have endocrine disrupting properties with respect to non-target organisms.

# **SECTION 3: Composition/information on ingredients**

#### Chemical characterization

Extract of herbal drugs

# **Further ingredients**

## Arachis hypogaea oil

CAS No. 8002-03-7 EINECS no. 232-296-4

Concentration >= 95 %

Advice: [4]



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Propane-1,2-diol

CAS No. 57-55-6 EINECS no. 200-338-0

Registration no. 01-2119456809-23

Concentration < 1 %
Advice: [4]

Advice. [4]

2,6-Di-tert-butyl-p-cresol

CAS No. 128-37-0 EINECS no. 204-881-4

Concentration < 1 %

[4]

Classification (Regulation (EC) No. 1272/2008)

Aquatic Chronic 1 H410

Concentration limits (Regulation (EC) No. 1272/2008)

Aquatic Chronic M = 1

1

6-O-palmitoylascorbic acid

CAS No. 137-66-6 EINECS no. 205-305-4

Concentration < 1 %

Advice: [4]

Classification (Regulation (EC) No. 1272/2008)

Eye Irrit. 2 H319

Stearic acid, monoester with glycerol

CAS No. 31566-31-1 EINECS no. 250-705-4

Concentration < 1 %

Advice: [4]

Citric acid, anhydrous

CAS No. 77-92-9 EINECS no. 201-069-1

Concentration < 1 %

Advice: [4]

Classification (Regulation (EC) No. 1272/2008)

Eye Irrit. 2 H319

Note

[4] Voluntary information

## Other information

The product is an article within the meaning of Article 3 No. 3 of the REACH Regulation and thus not to be labelled according to the CLP regulation. The compilation of the Safety Data sheet is not required according to Article 31 REACH Regulation for articles and is done on a voluntary basis.

# **SECTION 4: First aid measures**

## 4.1. Description of first aid measures

#### **General information**

No special measures necessary.



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#### After inhalation

No special measures required.

#### After skin contact

In general the product isn't skin irritating. Wash off with soap and water.

## After eye contact

In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. In case of irritation consult an oculist.

## After ingestion

No special measures required. In the event of symptoms take medical treatment.

# **SECTION 5: Firefighting measures**

# 5.1. Extinguishing media

# Suitable extinguishing media

Dry chemical extinguisher, Foam, Carbon dioxide

# Non suitable extinguishing media

Full water jet

# 5.2. Special hazards arising from the substance or mixture

In the event of fire the following can be released: Carbon monoxide (CO); Carbon dioxide (CO2); smoke; Avoid inhalation of smoke and vapours.

# 5.3. Advice for firefighters

## Special protective equipment for fire-fighting

Use personal protective clothing. In case of combustion use a suitable breathing apparatus.

# **SECTION 6: Accidental release measures**

## 6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Remove persons to safety. Keep away sources of ignition. High risk of slipping due to leakage/spillage of product.

## 6.2. Environmental precautions

Do not allow to enter drains or waterways. Do not discharge into the subsoil/soil. In case the product spills into sewage waters, immediately inform the authorities.

## 6.3. Methods and material for containment and cleaning up

Pick up mechanically. Send in suitable containers for recovery or disposal. Clean contaminated surfaces thoroughly with water.

#### 6.4. Reference to other sections

Refer to protective measures listed in Sections 7 and 8. Information regarding waste disposal, see Section 13.

# **SECTION 7: Handling and storage**

# 7.1. Precautions for safe handling

# Advice on protection against fire and explosion

Containers in danger should be cooled with water. Danger of inflammation when welding on empty containers.

## 7.2. Conditions for safe storage, including any incompatibilities

Storage classes



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Storage class according to TRGS 510 10 Flammable liquids

## Further information on storage conditions

Do not keep at temperatures above 25 °C. Keep away from sources of ignition. Protect from heat.

Protect from light.

# **SECTION 8: Exposure controls/personal protection**

# 8.1. Control parameters

## Derived No/Minimal Effect Levels (DNEL/DMEL)

2,6-Di-tert-butyl-p-cresol

Type of value Derived No Effect Level (DNEL)

Reference group Worker
Duration of exposure Long term
Route of exposure inhalative
Mode of action Systemic effects

Concentration 3.5 mg/m<sup>3</sup>

Type of value Derived No Effect Level (DNEL)

Reference group Worker
Duration of exposure Short term
Route of exposure dermal

Mode of action Systemic effects

Concentration 0.5 mg/kg

Propane-1,2-diol

Type of value Derived No Effect Level (DNEL)

Reference group General Population

Duration of exposure Long term
Route of exposure inhalative

Mode of action Systemic effects

Concentration 50 mg/m<sup>3</sup>

Type of value Derived No Effect Level (DNEL)

Reference group Worker
Duration of exposure Long term
Route of exposure inhalative
Mode of action Systemic effects

Concentration 168 mg/m³

Type of value Derived No Effect Level (DNEL)

Reference group General Population

Duration of exposure Long term
Route of exposure inhalative
Mode of action Local effects

Concentration 10 mg/m³

Type of value Derived No Effect Level (DNEL)

Reference group

Duration of exposure

Route of exposure

Mode of action

Worker

Long term

inhalative

Local effects

Concentration 10 mg/m<sup>3</sup>

## **Predicted No Effect Concentration (PNEC)**



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Citric acid, anhydrous

Type of value **PNEC** Type Freshwater Concentration

0.44 mg/l

Type of value **PNEC** Type Saltwater

Concentration 0.044 mg/l

Type of value **PNEC** 

Type Sewage treatment plant (STP)

Concentration 1000 mg/l

**PNEC** Type of value Type Sediment

Concentration 34.6 mg/kg

Type of value **PNEC** 

Type Marine sediment

Concentration 3.46 mg/kg

**PNEC** Type of value Type Soil

Concentration 33.1 mg/kg

2,6-Di-tert-butyl-p-cresol

Type of value **PNEC** Type Freshwater Concentration 0.199

μg/l

**PNEC** Type of value Type Saltwater

Concentration 0.0199 μg/l

Type of value **PNEC** Type Water Conditions Intermittend Concentration 1.99

μg/l

**PNEC** Type of value Type Sediment

Concentration 0.0996 mg/kg

**PNEC** Type of value

Type Marine sediment

Concentration 0.0096 mg/kg

**PNEC** Type of value Type Soil

Concentration 0.04769 mg/kg

Propane-1,2-diol

Type of value **PNEC** Type Soil

Concentration 50 mg/kg



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Type of value PNEC

Type Saltwater

Concentration 26 mg/l

Type of value PNEC

Type Sewage treatment plant (STP)

Concentration 20000 mg/l

Type of value PNEC
Type Freshwater

Concentration 260 mg/l

Type of value PNEC

Type Marine sediment

Concentration 57.2 mg/kg

Type of value PNEC

Type Freshwater sediment

Concentration 572 mg/kg

# 8.2. Exposure controls

## General protective and hygiene measures

Observe the usual precautions for handling chemicals. Avoid any contact with the body.

## Respiratory protection

Not necessary.

## Hand protection

Gloves (oil-resistant)

#### Eye protection

Tightly fitting safety glasses

## **Body protection**

Clothing as usual in the chemical industry.

# SECTION 9: Physical and chemical properties

## 9.1. Information on basic physical and chemical properties

Physical state liquid

Colour clear yellow to green

**Odour** characteristic

## Boiling point or initial boiling point and boiling range

Value > 300 °C
Remarks Information refers to the main component.

Flash point

Value > 200 °C Remarks Information refers to the main component.

**Decomposition temperature** 

Remarks Stable at ambient temperature.

Remarks To avoid thermal decomposition, do not overheat.

Vapour pressure

Remarks No data available

Density and/or relative density



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Value 0.910 to 0.925 g/cm<sup>3</sup>

## 9.2. Other information

Solubility in water

Remarks insoluble

# SECTION 10: Stability and reactivity

# 10.1. Reactivity

No decomposition if stored and applied as directed.

# 10.2. Chemical stability

No decomposition if stored and applied as directed.

## 10.3. Possibility of hazardous reactions

No decomposition if stored and applied as directed.

#### 10.4. Conditions to avoid

No decomposition if stored and applied as directed. Keep away from sources of heat and ignition. Protect from light and atmospheric moisture.

# 10.5. Incompatible materials

Strong oxidising agents, chlorine liquide, concentrated oxigen

# 10.6. Hazardous decomposition products

No hazardous decomposition products known when handled according to prescibed instructions.

# **SECTION 11: Toxicological information**

# 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008 Acute oral toxicity (Components)

<b>0</b> 14 1			
Citric	acid.	anhv	drous

Species rat

LD50 3000 mg/kg

6-O-palmitoylascorbic acid

Species rat

LD50 > 10000 mg/kg

6-O-palmitoylascorbic acid

Species mouse

LD50 25000 mg/kg

6-O-palmitoylascorbic acid

Species mammal, species unspecified

LD50 > 4000 mg/kg

Stearic acid, monoester with glycerol

Species rat

LD50 > 5000 mg/kg

2,6-Di-tert-butyl-p-cresol

Species Rats (male/female)

LD50 > 6000 mg/kg

Method OECD 401

Propane-1,2-diol

Species rat

LD50 22000 mg/kg

Method OECD 401

# **Acute dermal toxicity (Components)**



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mg/kg

Citric acid, anhydrous

Remarks No data available

6-O-palmitoylascorbic acid

Species guinea pig LD50 > 3000

Human

Stearic acid, monoester with glycerol

Duration of exposure 24 h

Remarks Based on available data, the classification criteria are not met.

2,6-Di-tert-butyl-p-cresol

Species Rats (male/female)

LD50 > 2000 mg/kg

Method OECD 402

Propane-1,2-diol

Species

Species rabbit

LD50 > 2000 mg/kg

Duration of exposure 24 h

Method OECD 402

Acute inhalative toxicity (Components)

Citric acid, anhydrous

Remarks Harmful by inhalation.

6-O-palmitoylascorbic acid

Remarks No data available.

Stearic acid, monoester with glycerol Species Human

Remarks Based on available data, the classification criteria are not met.

2,6-Di-tert-butyl-p-cresol

Remarks No data available.

Propane-1,2-diol

Species rabbit

LC50 317042 mg/m³

Duration of exposure 2 h

Method OECD 403 **Skin corrosion/irritation (Components)** 

Citric acid, anhydrous

Species rabbit

evaluation slightly irritant Method OECD 404

6-O-palmitoylascorbic acid

Species rabbit evaluation slightly irritant

6-O-palmitoylascorbic acid

Species Human evaluation non-irritant Method OECD 439

Stearic acid, monoester with glycerol

Species guinea pig

Remarks No effect of irritation known.

2,6-Di-tert-butyl-p-cresol

Species rabbit

Duration of exposure 4

evaluation non-irritant

h



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Method OECD 404

Propane-1,2-diol

evaluation irritant effect possible

Method OECD 404

# Serious eye damage/irritation (Components)

Citric acid, anhydrous

Species rabbit

evaluation irritant - risk of serious damage to eyes

Method OECD 405

6-O-palmitoylascorbic acid

Species rabbit evaluation irritant

Method Draize method

6-O-palmitoylascorbic acid

evaluation irritant
Method OECD 429

Stearic acid, monoester with glycerol

Species mammal, species unspecified

Remarks slightly irritating (Eye)

2,6-Di-tert-butyl-p-cresol

Species rabbit evaluation non-irritant Method OECD 405

Propane-1,2-diol

evaluation irritant effect possible

Method OECD 405

## **Sensitization (Components)**

Citric acid, anhydrous

Remarks No data available.

6-O-palmitoylascorbic acid

Species mouse

evaluation non-sensitizing Method OECD 429

Stearic acid, monoester with glycerol

Remarks No sensitation effect known.

2,6-Di-tert-butyl-p-cresol

evaluation non-sensitizing

Method in vitro Source ECHA

Propane-1,2-diol

Remarks Based on available data, the classification criteria are not met.

# Subacute, subchronic, chronic toxicity (Components)

6-O-palmitoylascorbic acid

Remarks Not applicable

Stearic acid, monoester with glycerol

Remarks Not applicable

2,6-Di-tert-butyl-p-cresol

Remarks No data available

Propane-1,2-diol

Remarks No data available.



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## **Mutagenicity (Components)**

Citric acid, anhydrous

evaluation No mutagenicity in the Ames-test.

Method in vitro Remarks negative

6-O-palmitoylascorbic acid

Remarks negative

6-O-palmitoylascorbic acid

Species Escherichia coli

evaluation No mutagenicity in the Ames-test.

Method OECD 471

6-O-palmitoylascorbic acid

Species Salmonella typhimurium

evaluation No mutagenicity in the Ames-test.

Method OECD 471

Stearic acid, monoester with glycerol

Remarks No data available.

2,6-Di-tert-butyl-p-cresol

Species Salmonella typhimurium

evaluation No mutagenicity in the Ames-test.

Remarks negative

2,6-Di-tert-butyl-p-cresol

Route of exposure intraperitoneal

Species mouse

evaluation No mutagenicity in the micronucleus test.

2,6-Di-tert-butyl-p-cresol

Route of exposure oral species rat (male) Remarks negative

Propane-1,2-diol

Remarks Based on available data, the classification criteria are not met.

## Reproduction toxicity (Components)

Citric acid, anhydrous

Remarks Indications of toxic effects are available from reproduction studies in

animals.

6-O-palmitoylascorbic acid

evaluation No negative effects

Stearic acid, monoester with glycerol Species rat

Remarks Indications of toxic effects are available from reproduction studies in

animals.

2,6-Di-tert-butyl-p-cresol

Remarks No data available.

Propane-1,2-diol

Remarks Based on available data, the classification criteria are not met.

## **Carcinogenicity (Components)**

Citric acid, anhydrous

Remarks No data available.

6-O-palmitoylascorbic acid

Remarks negative

Stearic acid, monoester with glycerol



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Species rat Remarks negative

2,6-Di-tert-butyl-p-cresol

Remarks No evidence available on carcinogenicity.

Propane-1,2-diol

Remarks No data available.

Specific Target Organ Toxicity (STOT) (Components)

Citric acid, anhydrous

Remarks Not applicable

6-O-palmitoylascorbic acid

Remarks Not applicable

Stearic acid, monoester with glycerol

Remarks Not applicable

2,6-Di-tert-butyl-p-cresol

Remarks No data available.

Propane-1,2-diol

Remarks Based on available data, the classification criteria are not met.

## 11.2 Information on other hazards

## **Endocrine disrupting properties with respect to humans**

This substance does not have endocrine disrupting properties with respect to humans.

#### Other information

By appropiate use of the product no health damage is known.

No toxicological data are available.

# **SECTION 12: Ecological information**

## 12.1. Toxicity

## Fish toxicity (Components)

Citric acid, anhydrous

Species golden orfe (Leuciscus idus)

LC50 440 to 760 mg/l

Duration of exposure 96 h

6-O-palmitoylascorbic acid

Species Salmo gairdneri

LC50 51 mg/l

Duration of exposure 96 h

Stearic acid, monoester with glycerol

Remarks No data available.

2,6-Di-tert-butyl-p-cresol

Species Oryzias latipes

LC50 5.3 mg/l

2,6-Di-tert-butyl-p-cresol

Species zebra fish (Brachydanio rerio)

LC50 > 0.57 mg/l

Duration of exposure 96 h

Method Directive 67/548/EEC, Annex V, C.1.

2,6-Di-tert-butyl-p-cresol

Species Oryzias latipes

NOEC 0.053 mg/l

Duration of exposure 30 d



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Method OECD 210

Propane-1,2-diol

Species rainbow trout (Oncorhynchus mykiss)

LC50 40613 mg/l

Duration of exposure 96 h

**Daphnia toxicity (Components)** 

Citric acid, anhydrous

EC5 485 mg/l

Source Entosiphon sulcatum (Literaturwert)

Citric acid, anhydrous

Species Daphnia magna

EC50 120 mg/l

Duration of exposure 72 h

6-O-palmitoylascorbic acid

Species Daphnia magna

EC50 > 100 mg/l

Duration of exposure 48 h

Method OECD 202

Stearic acid, monoester with glycerol

Remarks No data available.

2,6-Di-tert-butyl-p-cresol

Species Daphnia magna

EC50 0.48 mg/l

Duration of exposure 48 h

Method OECD 202

2,6-Di-tert-butyl-p-cresol

Species Daphnia magna

EC50 0.096 mg/l

Duration of exposure 21 d

Method OECD 211

Propane-1,2-diol

Species Ceriodaphnia dubia

LC50 18340 mg/l

Duration of exposure 48 h

Method static test

Source EPA 600/489/001

Propane-1,2-diol

Species Ceriodaphnia dubia

NOEC 13020 mg/l

Duration of exposure 7 d

Method US-EPA

Algae toxicity (Components)

Citric acid, anhydrous

Species Scenedesmus quadricauda

IC5 640 mg/l

Duration of exposure 7 d

Citric acid, anhydrous

Species Microcystis aeruginosa (blue alge)

IC5 80 mg/l

6-O-palmitoylascorbic acid

Species Pseudokirchneriella subcapitata

EC50 > 100 mg/l

Duration of exposure 72 h



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Method OECD 201

Stearic acid, monoester with glycerol

Remarks No data available.

2,6-Di-tert-butyl-p-cresol

Species Desmodesmus subspicatus

ErC50 > 0.4 mg/l

Duration of exposure 72 h

Method Regulation (EC) No. 440/2008, Annex, C.3

2,6-Di-tert-butyl-p-cresol

Species Desmodesmus subspicatus

EC10 0.4 mg/l

Duration of exposure 72 h

2,6-Di-tert-butyl-p-cresol

ErC50 > 0.24 mg/l

Duration of exposure 72 h

Method OECD 201

Propane-1,2-diol

Species Raphidocelis subcapitata

EC50 19000 mg/l

Duration of exposure 96 h

Method OECD 201

**Bacteria toxicity (Components)** 

Citric acid, anhydrous

EC5 > 10000 mg/l

Duration of exposure 16 h

6-O-palmitoylascorbic acid

Remarks No data available.

Stearic acid, monoester with glycerol

Remarks No data available.

2,6-Di-tert-butyl-p-cresol

Species activated sludge

EC50 > 10000 mg/l

Duration of exposure 3 h

Method OECD 209

Propane-1,2-diol

Species Pseudomonas putida

NOEC > 20000 mg/l

Duration of exposure 18 h

12.2. Persistence and degradability

Physico-chemical eliminability (Components)

Citric acid, anhydrous

Remarks No data available.

6-O-palmitoylascorbic acid

Remarks No data available.

Stearic acid, monoester with glycerol

Remarks No data available.

2,6-Di-tert-butyl-p-cresol

Remarks No data available.

Propane-1,2-diol

Remarks No data available.



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**Biodegradability (Components)** 

Citric acid, anhydrous

Value 98 %
Duration of test 2 d

evaluation Readily eliminable from water

6-O-palmitoylascorbic acid

Value 48 %

Duration of test 28 d

evaluation inherently biodegradable, fulfilling criteria

Method OECD 302 C

6-O-palmitoylascorbic acid

Value 93 %

Duration of test 28 d evaluation Readily biodegradable

Method OECD 301 B

Stearic acid, monoester with glycerol

Remarks No data available.

2,6-Di-tert-butyl-p-cresol

Value < 10 %

Duration of test 20 d evaluation not readily degradable

Method OECD 301D

Propane-1,2-diol

Remarks The product is biodegradable.

Ready degradability (Components)

Citric acid, anhydrous

Value 98 %
Duration of test 2 d

Method OECD 302B/ISO 9888/EEC 88/302,C

Stearic acid, monoester with glycerol

Remarks No data available.

2,6-Di-tert-butyl-p-cresol

Remarks Not readily biodegradable.

Propane-1,2-diol

Remarks No data available.

Chemical oxygen demand (COD) (Components)

Citric acid, anhydrous

Value 728 mg/g

Biochemical oxygen demand (BOD5) (Components)

Citric acid, anhydrous

Value 526 mg/g

Duration of test 5 d

12.3. Bioaccumulative potential

Octanol/water partition coefficient (log Pow) (Components)

Citric acid, anhydrous

log Pow -1.72

Temperature 20 °C

2,6-Di-tert-butyl-p-cresol

log Pow 5.1

Remarks Due to the distribution coefficient n-octanol/water, accumulation in



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organisms is possible.

## 12.4. Mobility in soil

# **Mobility in soil (Components)**

## 2,6-Di-tert-butyl-p-cresol

The product is insoluble and sinks in water.

## 2,6-Di-tert-butyl-p-cresol

Adsorbs on soil.

## 2,6-Di-tert-butyl-p-cresol

**Immobile** 

## 12.5. Results of PBT and vPvB assessment

#### Results of PBT and vPvB assessment

The Substance does not meet PBT-criteria. This substance does not meet the vPvB-criteria.

# 12.6 Endocrine disrupting properties

## Endocrine disrupting properties with respect to the envrionment

This substance does not have endocrine disrupting properties with respect to non-target organisms.

#### 12.7. Other adverse effects

## General information / ecology

Ecological data are not available.

# **SECTION 13: Disposal considerations**

# 13.1. Waste treatment methods

# Disposal recommendations for the product

Disposal in compliance with local and national regulations.

# Disposal recommendations for packaging

Dispose of as unused product.

# **SECTION 14: Transport information**

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

# SECTION 15: Regulatory information \*\*\*

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

## Water Hazard Class (Germany) \*\*\*

Water Hazard Class

Not water hazardous

(Germany)

Remarks Derivation of WGK according to Annex 1 No. 5.2 AwSV

# SECTION 16: Other information



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# **Supplemental information**

Relevant changes compared with the previous version of the safety data sheet are marked with: \*\*\* This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.