

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU

## **STABILIN PLUS**

Version number: GHS 2.0 Revision: 27.09.2023

Replaces version of: 11.05.2022 (GHS 1)

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

#### 1.1 Product identifier

Trade name STABILIN PLUS

Registration number (REACH) not relevant (mixture)

Article number 1003685

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

Relevant identified uses Premixture

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

Innovad NV/SA Postbaan 69 2910 Essen Belgium

Telephone: +32 (0)3 667 16 55

Website: https://innovad-global.com/

e-mail (competent person)

T.Rogge@innovad-global.com (Tina Rogge)

## 1.4 Emergency telephone number

Emergency information service +32 (0)3 667 16 55

This number is only available during office hours.

Poison centre

Country	Name	Telephone
Belgium	Belgisch antigifcentrum / Centre antipoisons Belge	070 245 245

#### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Category	Hazard class and cat- egory	Hazard state- ment
3.2	skin corrosion/irritation	1	Skin Corr. 1	H314
3.45	skin sensitisation	1	Skin Sens. 1	H317
4.1C	hazardous to the aquatic environment - chronic hazard	2	Aquatic Chronic 2	H411

For full text of abbreviations: see SECTION 16.

The most important adverse physicochemical, human health and environmental effects

Skin corrosion produces an irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis. Spillage and fire water can cause pollution of watercourses.

## 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Signal word danger

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#### - Pictograms

GHS05, GHS07, GHS09







#### - Hazard statements

H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

## - Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protec-

tion.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or

shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P362+P364 Take off contaminated clothing and wash it before reuse.

P391 Collect spillage.

P501 Dispose of contents/container to industrial combustion plant.

- Hazardous ingredients for labelling

Propyl gallate, Citric acid

#### 2.3 Other hazards

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of  $\geq$  0,1%.

**Endocrine disrupting properties** 

Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq$  0,1%.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not relevant (mixture)

#### 3.2 Mixtures

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
Butylated hydroxytolu- ene (BHT)	CAS No 128-37-0 EC No 204-881-4 REACH 01- Reg. No 21194804 33-40- xxxx 01- 21195552 70-46- xxxx 01- 21195651 13-46- xxxx	5-<10	Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410	

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Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
Propyl gallate	CAS No 121-79-9 EC No 204-498-2 Index No 607-198- 00-3 REACH 01- Reg. No 21207668 69-29- xxxx	5-<10	Acute Tox. 4 / H302 Skin Sens. 1 / H317	<u>(i)</u>
Citric acid	CAS No 77-92-9 EC No 201-069-1 Index No 607-750- 00-3 REACH 01- Reg. No 21194570 26-42- xxxx	1-<5	Skin Corr. 1 / H314 Eye Irrit. 2 / H319 STOT SE 3 / H335	
Sorbic acid	CAS No 110-44-1 EC No 203-768-7 REACH 01- Reg. No 21199503 30-49- xxxx	1-<5	Skin Irrit. 2 / H315 Eye Irrit. 2 / H319 STOT SE 3 / H335	<u>(!</u> )

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
Propyl gallate	-	-	>1.000 <sup>mg</sup> / <sub>kg</sub>	oral

For full text of abbreviations: see SECTION 16.

### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

#### General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

#### Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician. Provide fresh air.

#### Following skin contact

Rinse skin with water/shower.

## Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

#### Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

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

Symptoms and effects are not known to date.

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

none

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## **SECTION 5: Firefighting measures**

## 5.1 Extinguishing media

Suitable extinguishing media

Water, Foam, ABC-powder

Unsuitable extinguishing media

Water jet

#### 5.2 Special hazards arising from the substance or mixture

Deposited combustible dust has considerable explosion potential.

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO2)

### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

## **SECTION 6: Accidental release measures**

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

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

### **6.2** Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

## 6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains, Take up mechanically

Advice on how to clean up a spill

Take up mechanically.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

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## **SECTION 7: Handling and storage**

## 7.1 Precautions for safe handling

#### Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Take precautionary measures against static discharge. Use only in well-ventilated areas. Ground/bond container and receiving equipment.

- Specific notes/details

Dust deposits may accumulate on all deposition surfaces in a technical room. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

### Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

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

Managing of associated risks

- Explosive atmospheres
  - Removal of dust deposits.
- Ventilation requirements
   Use local and general ventilation.
- Packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used.

## 7.3 Specific end use(s)

See section 16 for a general overview.

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

#### 8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)

Coun try	Name of agent	CAS No	Iden- tifier	TWA [ppm]	TWA [mg/ m³]	STEL [ppm]	STEL [mg/ m³]	Ceil- ing-C [ppm]	Ceil- ing-C [mg/ m³]	Nota tion	Sourc e
BE	particulates not otherwise classi- fied		VLEP/ GWBB		10					-	Mon- iteur Belge
BE	particulates not otherwise classi- fied		VLEP/ GWBB		3					r	Mon- iteur Belge
BE	2,6-di-tert-butyl-p- cresol	128-37-0	VLEP/ GWBB		2					va	Mon- iteur Belge

Notation

Ceiling-C ceiling value is a limit value above which exposure should not occur

inhalable fraction respirable fraction

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Notation

STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute peri-

od (unless otherwise specified)

time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified) as vapours and aerosols TWA

va

## Relevant DNELs of components of the mixture

Name of sub- stance	CAS No	End- point	Threshold level	Protection goal, route of expos- ure	Used in	Exposure time
Butylated hydroxy- toluene (BHT)	128-37-0	DNEL	1,76 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic ef- fects
Butylated hydroxy- toluene (BHT)	128-37-0	DNEL	0,5 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic ef- fects
Propyl gallate	121-79-9	DNEL	6,66 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic ef- fects
Propyl gallate	121-79-9	DNEL	1,89 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic ef- fects
Sorbic acid	110-44-1	DNEL	17,63 mg/m³	human, inhalatory	worker (industry)	chronic - systemic ef- fects
Sorbic acid	110-44-1	DNEL	40 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

### Relevant PNECs of components of the mixture

Name of sub- stance	CAS No	End- point	Threshold level	Organism	Environmental compartment	Exposure time
Butylated hydroxy- toluene (BHT)	128-37-0	PNEC	0,199 <sup>µg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single in- stance)
Butylated hydroxy- toluene (BHT)	128-37-0	PNEC	0,02 <sup>µg</sup> / <sub>I</sub>	aquatic organisms	marine water	short-term (single in- stance)
Butylated hydroxy- toluene (BHT)	128-37-0	PNEC	0,017 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single in- stance)
Butylated hydroxy- toluene (BHT)	128-37-0	PNEC	0,458 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single in- stance)
Butylated hydroxy- toluene (BHT)	128-37-0	PNEC	0,046 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	marine sediment	short-term (single in- stance)
Butylated hydroxy- toluene (BHT)	128-37-0	PNEC	0,054 <sup>mg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single in- stance)
Propyl gallate	121-79-9	PNEC	0,37 <sup>µg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single in- stance)
Propyl gallate	121-79-9	PNEC	0,037 <sup>µg</sup> / <sub>l</sub>	aquatic organisms	marine water	short-term (single in- stance)
Propyl gallate	121-79-9	PNEC	6,36 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single in- stance)
Propyl gallate	121-79-9	PNEC	4,5 <sup>µg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single in- stance)

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## Relevant PNECs of components of the mixture

Name of sub- stance	CAS No	End- point	Threshold level	Organism	Environmental compartment	Exposure time
Propyl gallate	121-79-9	PNEC	0,45 <sup>µg</sup> / <sub>kg</sub>	aquatic organisms	marine sediment	short-term (single in- stance)
Propyl gallate	121-79-9	PNEC	0,688 <sup>µg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single in- stance)
Citric acid	77-92-9	PNEC	0,44 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single in- stance)
Citric acid	77-92-9	PNEC	0,044 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	marine water	short-term (single in- stance)
Citric acid	77-92-9	PNEC	1.000 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single in- stance)
Citric acid	77-92-9	PNEC	34,6 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single in- stance)
Citric acid	77-92-9	PNEC	3,46 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	marine sediment	short-term (single in- stance)
Citric acid	77-92-9	PNEC	33,1 <sup>mg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single in- stance)
Sorbic acid	110-44-1	PNEC	0,465 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single in- stance)
Sorbic acid	110-44-1	PNEC	0,046 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	marine sediment	short-term (single in- stance)
Sorbic acid	110-44-1	PNEC	5 <sup>mg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single in- stance)
Sorbic acid	110-44-1	PNEC	0,241 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	water	intermittent release
Sorbic acid	110-44-1	PNEC	0,01294 <sup>mg</sup> / <sub>I</sub>	aquatic organisms	marine water	short-term (single in- stance)
Sorbic acid	110-44-1	PNEC	0,129 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single in- stance)
Sorbic acid	110-44-1	PNEC	10 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single in- stance)

## 8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

Wear protective gloves.

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#### - Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

#### Respiratory protection

Particulate filter device (EN 143).

#### Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

## **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state	solid (powder)
Colour	white to yellowish/beige
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	>160 °C at 1.013 hPa
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	not determined
Flash point	not applicable
Auto-ignition temperature	>402 °C
Decomposition temperature	not relevant
pH (value)	5,5 – 6,5 (in aqueous solution: 100 <sup>g</sup> / <sub>l</sub> , 20 °C)
Kinematic viscosity	not relevant
Solubility(ies)	not determined

#### Partition coefficient

Partition coefficient n-octanol/water (log value)	this information is not available
Vapour pressure	0,011 hPa at 20 °C

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### Density and/or relative density

Density	0,77 – 0,87 <sup>kg</sup> / <sub>l</sub> at 20 °C
Relative vapour density	information on this property is not available

Particle characteristics	no data available

#### 9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
----------------------------------------------------	----------------------------------------------------------------

## Other safety characteristics

Liquid content	0,8 %
Solid content	99,2 %

## **SECTION 10: Stability and reactivity**

### 10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

#### 10.2 Chemical stability

See below "Conditions to avoid".

### 10.3 Possibility of hazardous reactions

No known hazardous reactions.

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

#### Hints to prevent fire or explosion

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

#### 10.5 Incompatible materials

Oxidisers

### 10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

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## **SECTION 11: Toxicological information**

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

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

## Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Shall not be classified as acutely toxic.

GHS of the United Nations, annex 4: May be harmful if swallowed or in contact with skin.

## Acute toxicity estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE
Propyl gallate	121-79-9	oral	>1.000 <sup>mg</sup> / <sub>kg</sub>

#### Skin corrosion/irritation

Causes severe skin burns and eye damage.

#### Serious eye damage/eye irritation

Causes serious eye damage.

### Respiratory or skin sensitisation

May cause an allergic skin reaction.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

#### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

## Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

### Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

#### Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

### 11.2 Information on other hazards

There is no additional information.

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## **SECTION 12: Ecological information**

## 12.1 Toxicity

Toxic to aquatic life with long lasting effects.

Aquatic toxicity (chronic) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Butylated hydroxytolu- ene (BHT)	128-37-0	EC50	0,096 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	21 d
Propyl gallate	121-79-9	EC50	636 <sup>mg</sup> / <sub>l</sub>	microorganisms	3 h
Sorbic acid	110-44-1	LC50	>50 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	21 d
Sorbic acid	110-44-1	EC50	>50 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	21 d

### 12.2 Persistence and degradability

Degradability of components of the mixture

Name of sub- stance	CAS No	Process	Degradation rate	Time	Method	Source
Propyl gallate	121-79-9	oxygen depletion	49,4 %	28 d		ECHA
Sorbic acid	110-44-1	oxygen depletion	74,9 %	28 d		ECHA

## 12.3 Bioaccumulative potential

Data are not available.

Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Butylated hydroxytoluene (BHT)	128-37-0		5,1	
Propyl gallate	121-79-9		1,8	
Sorbic acid	110-44-1	2,6	1,32 (pH value: 2,5)	

#### 12.4 Mobility in soil

Data are not available.

### 12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance in a concentration of  $\geq 0.1\%$ .

#### 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq$  0,1%.

#### 12.7 Other adverse effects

Data are not available.

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## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

#### Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

### **SECTION 14: Transport information**

14.1	UN n	umber	or ID	number
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ADR/RID/ADN UN 3077
IMDG-Code UN 3077
ICAO-TI UN 3077

14.2 UN proper shipping name

ADR/RID/ADN ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S.

IMDG-Code ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S.

ICAO-TI Environmentally hazardous substance, solid,

n.o.s.

Technical name (hazardous ingredients)

Butylated hydroxytoluene (BHT)

14.3 Transport hazard class(es)

ADR/RID/ADN 9
IMDG-Code 9
ICAO-TI 9

14.4 Packing group

ADR/RID/ADN III
IMDG-Code III
ICAO-TI III

**14.5** Environmental hazards hazardous to the aquatic environment

Environmentally hazardous substance (aquatic Butylated hydroxytoluene (BHT)

environment)

## 14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

#### 14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

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## 14.8 Information for each of the UN Model Regulations

# 14.8.2 Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

Particulars in the transport document UN3077, ENVIRONMENTALLY HAZARDOUS SUB-

STANCE, SOLID, N.O.S., (contains: Butylated hy-

droxytoluene (BHT)), 9, III, (-)

Classification code M7

Danger label(s) 9, fish and tree

Environmental hazards yes (hazardous to the aquatic environment)

Special provisions (SP) 274, 335, 375, 601

Excepted quantities (EQ)

Limited quantities (LQ)

Transport category (TC)

Tunnel restriction code (TRC)

Hazard identification No

5 kg

-

## International Maritime Dangerous Goods Code (IMDG) - Additional information

Marine pollutant Yes (hazardous to the aquatic environment) (Butylated hydroxy-

toluene (BHT))

Danger label(s) 9, fish and tree



Special provisions (SP) 274, 335, 966, 967, 969

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 kg
EmS F-A, S-F
Stowage category A

#### International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Environmental hazards yes (hazardous to the aquatic environment)

Danger label(s) 9, fish and tree

Special provisions (SP) A97, A158, A179, A197, A215

Excepted quantities (EQ) E1
Limited quantities (LQ) 30 kg

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## **SECTION 15: Regulatory information**

## Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

## Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Propyl gallate	substances in tattoo inks and perman- ent make-up		R75	75
Citric acid	substances in tattoo inks and perman- ent make-up		R75	75
Sorbic acid	substances in tattoo inks and permanent make-up		R75	75

#### Legend

- 1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:
- (a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
- (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight; (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight; (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A,
- 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:
- (i) 0,1 % by weight, if the substance is used solely as a pH regulator;
- (ii) 0,01 % by weight, in all other cases;
- (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
- (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:
- (i) "Rinse-off products"
- (ii) "Not to be used in products applied on mucous membranes";
- (iii) "Not to be used in eye products"
- (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration
- equal to or greater than the concentration limit specified for that substance in that Appendix.
- 2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design
- 3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

- 4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
  (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
  (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
  5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
- 6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

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#### Legend

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(b) a reference number to uniquely identify the batch;

(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this

(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;

(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;

(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a),

shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.

8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattoo-

ing purposes

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

### List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

none of the ingredients are listed

## **Deco-Paint Directive**

VOC content	1,238 %
Industrial Emissions Directive (IED)	
VOC content	0 %

## Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

#### Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

#### Water Framework Directive (WFD)

none of the ingredients are listed

## Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

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# National inventories

Country	Inventory	Status
EU	REACH Reg.	not all ingredients are listed

Legend

REACH Reg. REACH registered substances

## 15.2 Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

## **SECTION 16: Other information**

## Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
1.4		Poison centre: change in the listing (table)	yes
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1	The most important adverse physicochemical, human health and environmental effects: Spillage and fire water can cause pollution of watercourses.	The most important adverse physicochemical, human health and environmental effects: Skin corrosion produces an irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis. Spillage and fire water can cause pollution of watercourses.	yes
2.2	- Signal word: warning	- Signal word: danger	yes
2.2		- Pictograms: change in the listing (table)	yes
2.2		- Hazard statements: change in the listing (table)	yes
2.2		- Precautionary statements: change in the listing (table)	yes
2.2	- Hazardous ingredients for labelling: Propyl gallate	- Hazardous ingredients for labelling: Propyl gallate, Citric acid	yes
2.3	Other hazards: of no significance	Other hazards	yes
2.3		Results of PBT and vPvB assessment: Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.	yes
2.3		Endocrine disrupting properties:  Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.	yes
3.2		Description of the mixture: change in the listing (table)	yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
4.1	Following inhalation: If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.	Following inhalation: If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician. Provide fresh air.	yes
8.1		Occupational exposure limit values (Workplace Exposure Limits): change in the listing (table)	yes
9.2	Solvent content: 0,965 %	Liquid content: 0,8 %	yes
11.1	Skin corrosion/irritation: Shall not be classified as corrosive/irritant to skin.	Skin corrosion/irritation: Causes severe skin burns and eye damage.	yes
11.1	Serious eye damage/eye irritation: Shall not be classified as seriously damaging to the eye or eye irritant.	Serious eye damage/eye irritation: Causes serious eye damage.	yes
12.5	Results of PBT and vPvB assessment: Data are not available.	Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.	yes
12.6	Endocrine disrupting properties: None of the ingredients are listed.	Endocrine disrupting properties: Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.	yes
14.8.2		Particulars in the transport document: UN3077, ENVIRONMENTALLY HAZARDOUS SUB- STANCE, SOLID, N.O.S., (contains: Butylated hy- droxytoluene (BHT)), 9, III, (-)	yes
15.1	VOC content: 2,203 %	VOC content: 1,238 %	yes
15.1	VOC content: 0,965 %	VOC content: 0 %	yes
15.1		National inventories	yes
15.1		National inventories: change in the listing (table)	yes
16		List of relevant phrases (code and full text as stated in section 2 and 3): change in the listing (table)	yes

## **Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de naviga- tion intérieures (European Agreement concerning the International Carriage of Dangerous Goods by In- land Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)

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Abbr.	Descriptions of used abbreviations
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
log KOW	n-Octanol/water
Moniteur Belge	Arrêté royal modifiant l'arrêté royal du 11 mars 2002 relatif à la protection de la santé et de la sécurité des travailleurs contre les risques liés à des agents chimiques sur le lieu de travail

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Abbr. **Descriptions of used abbreviations** NLP No-Longer Polymer PBT Persistent, Bioaccumulative and Toxic **PNEC Predicted No-Effect Concentration** ppm Parts per million Registration, Evaluation, Authorisation and Restriction of Chemicals **REACH** RID Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail) Skin Corr. Corrosive to skin Skin Irrit. Irritant to skin Skin Sens. Skin sensitisation STEL Short-term exposure limit STOT SE Specific target organ toxicity - single exposure SVHC Substance of Very High Concern **TWA** Time-weighted average VOC Volatile Organic Compounds vPvB Very Persistent and very Bioaccumulative

### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

### Classification procedure

Physical and chemical properties: The classification is based on tested mixture. Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

### List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

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#### **Disclaimer**

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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