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



#### Aristolochic acid II ROTICHROM® HPLC

article number: 1088 Version: 3.0 en Replaces version of: 17.02.2022 Version: (2)

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

**Product identifier** 1.1

Identification of the substance

Article number

Registration number (REACH)

Aristolochic acid II ROTICHROM® HPLC

1088

It is not required to list the identified uses because the substance is not subject to registration according to REACH (< 1 t/a).

EC number

CAS number

207-499-6

475-80-9

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

Relevant identified uses:

Uses advised against:

Laboratory chemical Laboratory and analytical use

Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household). Food, drink and animal feedingstuffs.

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

Carl Roth GmbH + Co. KG Schoemperlenstr. 3-5 D-76185 Karlsruhe Germany

Telephone:+49 (0) 721 - 56 06 0 Telefax: +49 (0) 721 - 56 06 149 e-mail: sicherheit@carlroth.de Website: www.carlroth.de

Competent person responsible for the safety data Department Health, Safety and Environment sheet:

e-mail (competent person):

#### sicherheit@carlroth.de

#### **Emergency telephone number** 1.4

# **SECTION 2: Hazards identification**

2.1 Classification of the substance or mixture

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

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.10	Acute toxicity (oral)	3	Acute Tox. 3	H301
3.1D	Acute toxicity (dermal)	3	Acute Tox. 3	H311
3.1I	Acute toxicity (inhal.)	3	Acute Tox. 3	H331
3.5	Germ cell mutagenicity	2	Muta. 2	H341

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Section	tion Hazard class		Hazard class and category	Hazard statement
3.6	Carcinogenicity	2	Carc. 2	H351

For full text of abbreviations: see SECTION 16

#### 2.2 Label elements

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

#### Signal word Danger

#### **Pictograms**

GHS06, GHS08



#### Hazard statements

H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled
H341	Suspected of causing genetic defects
H351	Suspected of causing cancer

#### **Precautionary statements**

#### Precautionary statements - prevention

P261	Avoid breathing dust
P280	Wear protective gloves/eye protection

#### **Precautionary statements - response**

P302+P352	IF ON SKIN: Wash with plenty of water
P308+P313	IF exposed or concerned: Get medical advice/attention

For professional users only

#### Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Symbol(s)



H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
P261	Avoid breathing dust.
P280	Wear protective gloves/eye protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P308+P313	IF exposed or concerned: Get medical advice/attention.

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#### 2.3 Other hazards

#### Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

#### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ .

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

#### 3.1 Substances

Name of substance	Aristolochic acid II
Molecular formula	$C_{16}H_9NO_6$
Molar mass	311,3 <sup>g</sup> / <sub>mol</sub>
CAS No	475-80-9
EC No	207-499-6

# Substance, Specific Conc. Limits, M-factors, ATE Specific Conc. Limits M-Factors ATE Exposure route $\frac{300 \text{ mg/kg}}{1.000 \text{ mg/kg}}$ oral dermal inhalation: dust/ mist

# **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures



#### **General notes**

Take off immediately all contaminated clothing. Self-protection of the first aider.

#### **Following inhalation**

Call a physician immediately. If breathing is irregular or stopped, administer artificial respiration.

#### Following skin contact

Rinse skin with water/shower. After contact with skin, wash immediately with plenty of water.

#### Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

#### **Following ingestion**

Rinse mouth immediately and drink plenty of water. Call a physician immediately. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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

Symptoms and effects are not known to date.

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



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# **4.3 Indication of any immediate medical attention and special treatment needed** none

# **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media



#### Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings! water, foam, dry extinguishing powder, ABC-powder

#### Unsuitable extinguishing media

water jet

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

Non-combustible.

#### Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus. Wear full chemical protective clothing.

# **SECTION 6: Accidental release measures**

6.1 Personal precautions, protective equipment and emergency procedures



#### For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe dust.

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

#### 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. Control of dust.

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

#### 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.

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

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# **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Use extractor hood (laboratory). Handle and open container with care. Avoid exposure. Avoid dust formation. Clear contaminated areas thoroughly.

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

Removal of dust deposits.

#### Advice on general occupational hygiene

When using do not eat or drink. Thorough skin-cleansing after handling the product.

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

Store in a dry place. Keep in a cool place. Direct light irradiation.

#### Incompatible substances or mixtures

Observe hints for combined storage.

#### Consideration of other advice:

Store locked up.

#### **Ventilation requirements**

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted. Use local and general ventilation.

#### Specific designs for storage rooms or vessels

Recommended storage temperature: 2 - 8 °C

#### 7.3 Specific end use(s)

No information available.

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

#### 8.1 Control parameters

#### **National limit values**

#### **Occupational exposure limit values (Workplace Exposure Limits)**

This information is not available.

#### 8.2 Exposure controls

#### Individual protection measures (personal protective equipment)

#### Eye/face protection



Use safety goggle with side protection.

#### Skin protection



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



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#### hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

#### • type of material

NBR (Nitrile rubber)

#### material thickness

>0,11 mm

#### • breakthrough times of the glove material

>480 minutes (permeation: level 6)

#### • other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

#### **Respiratory protection**



Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P1 (filters at least 80 % of airborne particles, colour code: White).

#### **Environmental exposure controls**

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
Form	powder, crystalline
Colour	yellow-orange
Odour	odourless
Melting point/freezing point	270 °C
Boiling point or initial boiling point and boiling range	not determined
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not applicable
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	not applicable

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Kinematic viscosity	not relevant
Solubility(ies)	
Water solubility	(practically insoluble)
Partition coefficient	
Partition coefficient n-octanol/water (log value):	this information is not available
Vapour pressure	not determined
Density and/or relative density	
Density	not determined
Relative vapour density	Information on this property is not available.
Particle characteristics	No data available.
Other safety parameters	
Oxidising properties	none
Other information	
Information with regard to physical hazard classes:	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics:	There is no additional information.

# **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

9.2

This material is not reactive under normal ambient conditions.

#### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

#### 10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser

#### 10.4 Conditions to avoid

Direct light irradiation. Keep away from heat.

#### **10.5** Incompatible materials

There is no additional information.

#### **10.6** Hazardous decomposition products

Hazardous combustion products: see section 5.

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



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# **SECTION 11: Toxicological information**

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

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

#### Acute toxicity

Toxic if swallowed. Toxic in contact with skin. Toxic if inhaled.

Acute toxicity	
----------------	--

Exposure route	Endpoint	Value	Species	Method	Source
dermal	LD50	1.000 <sup>mg</sup> / <sub>kg</sub>	monkey		
inhalation: dust/ mist	LC50	1 <sup>mg</sup> /ı/4h	monkey		

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

#### Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

#### **Respiratory or skin sensitisation**

Shall not be classified as a respiratory or skin sensitiser.

#### Germ cell mutagenicity

Suspected of causing genetic defects.

#### Carcinogenicity

Suspected of causing cancer.

#### **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.

#### Symptoms related to the physical, chemical and toxicological characteristics

#### • If swallowed

Liver and kidney damage

#### • If in eyes

slightly irritant but not relevant for classification

#### If inhaled

Irritating to respiratory system

#### • If on skin

Irritating to skin

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



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#### Other information

none

- **11.2** Endocrine disrupting properties Does not contain an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ .
- **11.3** Information on other hazards

There is no additional information.

# **SECTION 12: Ecological information**

#### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

#### 12.2 Persistence and degradability

Theoretical Oxygen Demand (without nitrification): 1,491  $^{mg}/_{mg}$ Theoretical Oxygen Demand (with nitrification): 1,696  $^{mg}/_{mg}$ Theoretical Carbon Dioxide: 2,262  $^{mg}/_{mg}$ 

#### 12.3 Bioaccumulative potential

Data are not available.

#### 12.4 Mobility in soil

Data are not available.

- **12.5 Results of PBT and vPvB assessment** Data are not available.
- 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\ge 0,1\%$ .

#### 12.7 Other adverse effects

Data are not available.

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

#### Waste treatment of containers/packagings

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

#### **13.2** Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

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



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#### Properties of waste which render it hazardous

HP 6 acute toxicity

HP 7 carcinogenic HP 11 mutagenic

#### **HP II** Mula

#### 13.3 Remarks

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

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

#### 14.1 UN number or ID number

17.1		
	ADR	UN 1544
	IMDG-Code	UN 1544
	ICAO-TI	UN 1544
14.2	UN proper shipping name	
	ADR	ALKALOID SALTS, SOLID, N.O.S.
	IMDG-Code	ALKALOID SALTS, SOLID, N.O.S.
	ICAO-TI	Alkaloid salts, solid, n.o.s.
	Technical name	Aristolochic acid II
14.3	Transport hazard class(es)	
	ADR	6.1
	IMDG-Code	6.1
	ICAO-TI	6.1
14.4	Packing group	
	ADR	III
	IMDG-Code	III
	ICAO-TI	III
14.5	Environmental hazards	non-environmentally hazardous acc. to the dan- gerous goods regulations

#### 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.

#### 14.8 Information for each of the UN Model Regulations

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



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Agreement concerning the International Carr information	iage of Dangerous Goods by Road (ADR)Additional
Proper shipping name	ALKALOID SALTS, SOLID, N.O.S.
Particulars in the transport document	UN1544, ALKALOID SALTS, SOLID, N.O.S., (Aristo- lochic acid II), 6.1, III, (E)
Classification code	T2
Danger label(s)	6.1
Special provisions (SP)	43, 274, 802(ADN)
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
Transport category (TC)	2
Tunnel restriction code (TRC)	E
Hazard identification No	60
International Maritime Dangerous Goods Cod	e (IMDG) - Additional information
Proper shipping name	ALKALOID SALTS, SOLID, N.O.S.
Particulars in the shipper's declaration	UN1544, ALKALOID SALTS, SOLID, N.O.S., (Aristo- lochic acid II), 6.1, III
Marine pollutant	-
Danger label(s)	6.1
<b>**</b> 5	
Special provisions (SP)	43, 223, 274
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
EmS	F-A, S-A
Stowage category	A
International Civil Aviation Organization (ICA	O-IATA/DGR) - Additional information
Proper shipping name	Alkaloid salts, solid, n.o.s.
Particulars in the shipper's declaration	UN1544, Alkaloid salts, solid, n.o.s., (Aristolochic acid II), 6.1, III
Danger label(s)	6.1
Special provisions (SP)	A3, A5, A6
Excepted quantities (EQ)	E1
Limited quantities (LQ)	10 kg

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



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# **SECTION 15: Regulatory information**

#### 15.1 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
Aristolochic acid II	substances in tattoo inks and perman- ent 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 sub-stances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or R75 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 cat-egory 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: 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; mixture in a concentration equal to or greater than 0,00005 % by weight: (i) "Rinse-off products"; (i) "Not to be used in products applied on mucous membranes";
(ii) "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 in the conduction specified for that substance is present. (n) 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 on his or her body.
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 strictest is paragraph 1 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 apthat it then falls within a different one of those points from the one within which it fell previously, and the date of ap-plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, para-graph 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. 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"; (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. Im-writing the herearded as ingredients is 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

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



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this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredi-(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 concentra-

tion 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 1272/2008.

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

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or gener-ate 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 200-001-8).

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 Device 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

Not listed.

#### **Seveso Directive**

2012/	2012/18/EU (Seveso III)			
Νο	Dangerous substance/hazard categories	Qualifying quantity plication of lower quirer		Notes
H2	acute toxic (cat. 2 + cat. 3, inhal.)	50	200	41)

Notation

- Category 2, all exposure routes 41)

- category 3, inhalation exposure route

#### **Deco-Paint Directive**

VOC content	0 %

#### Industrial Emissions Directive (IED)

VOC content	0 %
-------------	-----

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

not listed

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

not listed

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



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Water Framework Directive (WFD)

#### article number: 1088

ist of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Aristolochic acid II	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment		a)	

#### Legend

Indicative list of the main pollutants a)

#### Regulation on the marketing and use of explosives precursors

not listed

#### **Regulation on drug precursors**

not listed

#### Regulation on substances that deplete the ozone layer (ODS)

not listed

#### Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

#### **Regulation on persistent organic pollutants (POP)**

not listed

#### Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

#### National inventories

Country	Inventory	Status
EU	ECSI	substance is listed
TW	TCSI	substance is listed
VN	NCI	substance is listed

Legend

ECSI EC Substance Inventory (EINECS, ELINCS, NLP) NCI TCSI

National Chemical Inventory Taiwan Chemical Substance Inventory

#### 15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance.

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



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# **SECTION 16: Other information**

#### Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.2		Hazard statements: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
14.2	ICAO-TI: Alkaloids, solid, n.o.s.	ICAO-TI: Alkaloid salts, solid, n.o.s.	yes
14.8	Proper shipping name: Alkaloids, solid, n.o.s.	Proper shipping name: Alkaloid salts, solid, n.o.s.	yes
14.8	Particulars in the shipper's declaration: UN1544, Alkaloids, solid, n.o.s., (Aristolochic acid II), 6.1, III	Particulars in the shipper's declaration: UN1544, Alkaloid salts, solid, n.o.s., (Aristoloch- ic acid II), 6.1, III	yes
15.1		National inventories: change in the listing (table)	yes

#### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concern- ing the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identi- fier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Na- tions
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

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



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Abbr.	Descriptions of used abbreviations
IMDG-Code	International Maritime Dangerous Goods Code
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SVHC	Substance of Very High Concern
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.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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

Code	Text
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.

#### Disclaimer

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