according to Regulation (EC) No. 1907/2006 (REACH)

# Aristolochic acid I ROTICHROM® HPLC

article number: 1086 date of compilation: 2016-11-17 Version: **2.0 en** Revision: 2022-02-17

Replaces version of: 2016-11-17

Version: (1)



#### **Product identifier** 1.1

Identification of the substance Aristolochic acid I ROTICHROM® HPLC

Article number 1086

Registration number (REACH) It is not required to list the identified uses be-

cause the substance is not subject to registration

according to REACH (< 1 t/a).

EC number 206-238-3 CAS number 313-67-7

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

Relevant identified uses: Laboratory chemical

Laboratory and analytical use

Uses advised against: Do not use for products which come into contact

with foodstuffs. Do not use for private purposes

(household).

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

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

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

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Service City Hospital	Dudley Rd	B187QH Birmingham	844 892 0111	

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## **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
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 Suspected of causing genetic defects (if exposed)
H351 Suspected of causing cancer (if exposed)

#### **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)





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H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.
H341 Suspected of causing genetic defects (if exposed).

H351 Suspected of causing cancer (if exposed).

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.

#### 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.

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

#### 3.1 Substances

Name of substance Aristolochic acid I

Molecular formula  $C_{17}H_{11}NO_7$  Molar mass  $341,3\,^g/_{mol}$  CAS No 313-67-7 EC No 206-238-3

#### Substance, Specific Conc. Limits, M-factors, ATE

Specific Conc. Limits	M-Factors	ATE	Exposure route
-		184 <sup>mg</sup> / <sub>kg</sub> 500 <sup>mg</sup> / <sub>kg</sub> 1 <sup>mg</sup> / <sub>l</sub> /4h	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).

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## 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

# **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

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.

#### 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.

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#### 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.

# 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)**

Coun	Name of agent	CAS No	Identifi- er	TWA [mg/ m³]	STEL [mg/ m³]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
GB	dust		WEL	10			i	EH40/2005
GB	dust		WEL	4			r	EH40/2005

Notation

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

Inhalable fraction Respirable fraction

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

minute period (unless otherwise specified)

TWA 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)

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

#### **Eye/face protection**





Use safety goggle with side protection.

#### Skin protection





#### 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.

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#### 8.2 **Exposure controls**

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

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

Physical state solid

Form powder, crystalline
Colour not determined

Odour odourless
Melting point/freezing point 280 °C

Boiling point or initial boiling point and boiling

range

not determined

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit not determined

Flash point not applicable

Auto-ignition temperature not determined

Decomposition temperature not relevant

pH (value) not applicable

Kinematic viscosity not relevant

Solubility(ies)

Water solubility (poorly soluble)

Partition coefficient

Partition coefficient n-octanol/water (log value): 4,19

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

9.2 Other information

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

Other safety characteristics: There is no additional information.

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# **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

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

#### 10.2 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

Keep away from heat.

#### 10.5 Incompatible materials

There is no additional information.

#### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

# **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
oral	LD50	184 <sup>mg</sup> / <sub>kg</sub>	rat		TOXNET

#### 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 (if exposed).

#### Carcinogenicity

Suspected of causing cancer (if exposed).

#### 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).

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#### 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

Data are not available.

#### If inhaled

Data are not available.

#### • If on skin

localised redness, irritant effects, pruritis

#### Other information

none

#### 11.2 Endocrine disrupting properties

Not listed.

#### 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.

#### **Biodegradation**

Data are not available.

#### 12.2 Process of degradability

Data are not available.

#### 12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	4,19

#### 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

Not listed.

### 12.7 Other adverse effects

Data are not available.

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# **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.

#### 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. Waste catalogue ordinance (Germany).

#### 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.

# **SECTION 14: Transport information**

14.1	UN	numl	ber or	ID	number

ADRRID UN 1544
IMDG-Code UN 1544
ICAO-TI UN 1544

#### 14.2 UN proper shipping name

ADRRID ALKALOID SALTS, SOLID, N.O.S. IMDG-Code ALKALOID SALTS, SOLID, N.O.S.

ICAO-TI Alkaloids, solid, n.o.s.

Technical name Aristolochic acid I

#### 14.3 Transport hazard class(es)

ADRRID 6.1 IMDG-Code 6.1 ICAO-TI 6.1

#### 14.4 Packing group

ADRRID III
IMDG-Code III
ICAO-TI III

## **14.5 Environmental hazards** non-environmentally hazardous acc. to the dan-

gerous goods regulations

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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

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

Proper shipping name ALKALOID SALTS, SOLID, N.O.S.

Particulars in the transport document UN1544, ALKALOID SALTS, SOLID, N.O.S., (Aristo-

lochic acid I), 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

**Emergency Action Code** 2X

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)Additional information

Classification code 6.1

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
Hazard identification No 60

International Maritime Dangerous Goods Code (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 I), 6.1, III

Marine pollutant -

Danger label(s) 6.1

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Special provisions (SP) 43, 223, 274

Excepted quantities (EQ) Limited quantities (LQ) 5 kg **EmS** F-A, S-A

Stowage category

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

Proper shipping name Alkaloids, solid, n.o.s.

Particulars in the shipper's declaration UN1544, Alkaloids, solid, n.o.s., (Aristolochic acid

I), 6.1, III

Danger label(s) 6.1

Special provisions (SP) A3, A5, A6

Excepted quantities (EQ) E1 Limited quantities (LQ) 10 kg

# **SECTION 15: Regulatory information**

#### Safety, health and environmental regulations/legislation specific for the substance or mixture 15.1 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 I	substances in tattoo inks and permanent make-up		R75	75

#### Legend

R75

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

(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 or 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";

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(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 on his or her body.

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 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

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.

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:

7. Suppliers placing a mixture on the market for use for tattooling pullposes shall ensure that, after + 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 values of the ingredients at the time of formulation "Ingredient" means be listed in descending order by weight or volume of the ingredients at the time of formulation. "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 Regulation; (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 conciding in Appendix 12:

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 para-

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

tattooing 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 200-001-8).

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 Regulation shall apply cumulatively. Regulation shall apply cumulatively.

List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list Not listed.

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#### **Seveso Directive**

2012/18/EU (Seveso III)						
No	Dangerous substance/hazard categories	Qualifying quantity plication of lower a quiren		Notes		
H2	acute toxic (cat. 2 + cat. 3, inhal.)	50	200	41)		

#### Notation

- Category 2, all exposure routes - category 3, inhalation exposure route

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

VOC content 0 %	
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#### **Industrial Emissions Directive (IED)**

VOC content	0 %
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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

#### **Water Framework Directive (WFD)**

### **List of pollutants (WFD)**

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Aristolochic acid I	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

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

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#### 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
KR	KECI	substance is listed
TW	TCSI	substance is listed

Legend

ECSI KECI TCSI EC Substance Inventory (EINECS, ELINCS, NLP) Korea Existing Chemicals Inventory Taiwan Chemical Substance Inventory

#### 15.2 Chemical Safety Assessment

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

# **SECTION 16: Other information**

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

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

Restructuring: section 9, section 14

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1	Remarks: For full text of Hazard- and EU Hazard-state- ments: see SECTION 16.		yes
2.2		Pictograms: change in the listing (table)	yes
2.2		Hazard statements: change in the listing (table)	yes
2.2		Precautionary statements - response: change in the listing (table)	yes
2.2	Precautionary statements - storage		yes
2.2		Precautionary statements - storage: 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
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.3	Other hazards: There is no additional information.	Other hazards	yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.3		Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.	yes

# **Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations
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)
ATE	Acute Toxicity Estimate
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
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 identifier of substances commercially available within the EU (European Union)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/)
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 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
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
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern

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Abbr.	Descriptions of used abbreviations
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

#### 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). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). 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 (if exposed).
H351	Suspected of causing cancer (if exposed).

#### **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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