



Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Version: 1.0

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

1.1. Product identifier Product form : Substance Substance name : Aescin Product code 201700090 : 1.2. Relevant identified uses of the substance or mixture and uses advised against 1.2.1. Relevant identified uses Main use category : The product is intended for research, analysis and scientific education. Use of the substance/mixture : For professional use only : Laboratory chemicals Function or use category 1.2.2. Uses advised against Restrictions on use : Do not use : Ingestion, Inhalation, Dermal 1.3. Details of the supplier of the safety data sheet European Directorate for the Quality of Medicines & Healthcare EDQM, Council of Europe 7, Allée Kastner, CS30026 F-67081 Strasbourg France T +33(0)388412035 - F +33(0)388412771 sds@edqm.eu - www.edqm.eu 1.4. Emergency telephone number Emergency number : +33(0)390215608 **SECTION 2: Hazards identification** 2.1. Classification of the substance or mixture Classification according to Regulation (EC) No. 1272/2008 [CLP] H302 Acute toxicity (oral), Category 4 Full text of H- and EUH-statements: see section 16 Adverse physicochemical, human health and environmental effects Expert judgement and weight of evidence determination. 2.2. Label elements Labelling according to Regulation (EC) No. 1272/2008 [CLP] Hazard pictograms (CLP) GHS07 Signal word (CLP) : Warning Hazard statements (CLP) : H302 - Harmful if swallowed. Precautionary statements (CLP) : P301+P312 - IF SWALLOWED: Call a POISON CENTER if you feel unwell.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

No labelling required

2.3. Other hazards

No additional information available

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3.1. Substances			
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Aescin	-	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=833 mg/kg bodyweight)
Full text of H- and EUH-statements: see secti	ion 16		
3.2. Mixtures			
SECTION 4. Eirst sid massures			
4.1. Description of first aid measures	: Wipe off as much as possib		n, soft, absorbent material).
4.1. Description of first aid measures First-aid measures after skin contact First-aid measures after eye contact	: Wipe off as much as possik : Rinse eyes with water as a		, soft, absorbent material).
4.1. Description of first aid measures First-aid measures after skin contact First-aid measures after eye contact 4.2. Most important symptoms and ef	: Wipe off as much as possik : Rinse eyes with water as a		i, soft, absorbent material).
4.1. Description of first aid measures First-aid measures after skin contact First-aid measures after eye contact 4.2. Most important symptoms and ef No additional information available	: Wipe off as much as possik : Rinse eyes with water as a ffects, both acute and delayed	precaution.	ı, soft, absorbent material).
SECTION 4: First aid measures 4.1. Description of first aid measures First-aid measures after skin contact First-aid measures after eye contact 4.2. Most important symptoms and eff No additional information available 4.3. Indication of any immediate mediant No additional information available	: Wipe off as much as possik : Rinse eyes with water as a ffects, both acute and delayed	precaution.	, soft, absorbent material).
 4.1. Description of first aid measures First-aid measures after skin contact First-aid measures after eye contact 4.2. Most important symptoms and ef No additional information available 4.3. Indication of any immediate medi 	: Wipe off as much as possik : Rinse eyes with water as a ffects, both acute and delayed ical attention and special treatm	precaution.	ı, soft, absorbent material).
 4.1. Description of first aid measures First-aid measures after skin contact First-aid measures after eye contact 4.2. Most important symptoms and ef No additional information available 4.3. Indication of any immediate medi No additional information available 	: Wipe off as much as possik : Rinse eyes with water as a ffects, both acute and delayed ical attention and special treatm	precaution.	ı, soft, absorbent material).

Fire hazard	: See Heading 2.2.
5.3. Advice for firefighters	
Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.

SECTION 6: Accidental release measures		
6.1. Personal precautions, protective equipment and emergency procedures		
6.1.1. For non-emergency personnelEmergency procedures6.1.2. For emergency respondersNo additional information available	: Avoid all unnecessary exposure.	
6.2. Environmental precautions		
No additional information available		
6.3. Methods and material for containment	and cleaning up	
No additional information available		

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6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

No additional information available

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

No additional information available

8.2.2.2. Skin protection

Skin and body protection: Lab coat

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

No additional information available

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

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SECTION 9: Physical and chemical properties 9.1. Information on basic physical and chemical properties		
Colour	: Not available	
Appearance	: Powder.	
Odour	: Not available	
Odour threshold	: Not available	
Melting point	: 219 – 226 °C	
Freezing point	: Not available	
Boiling point	: Not available	
Flammability	: Not available	
Explosive limits	: Not applicable	
Lower explosion limit	: Not applicable	
Upper explosion limit	: Not applicable	
Flash point	: Not applicable	
Auto-ignition temperature	: Not applicable	
Decomposition temperature	: Not available	
рН	: 2,5 – 3,5	
pH solution	: Not available	
Viscosity, kinematic	: Not applicable	
Solubility	: Not available	
Partition coefficient n-octanol/water (Log Kow)	: Not available	
Vapour pressure	: Not available	
Vapour pressure at 50°C	: Not available	
Density	: Not available	
Relative density	: Not available	
Relative vapour density at 20°C	: Not applicable	
Particle size	: Not available	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

None under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

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11.1. Information on hazard classes	as defined in Regulation (EC) No 1272/2008
Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Aescin	
LD50 oral rat	300 – 2000 mg/kg
Skin corrosion/irritation	: Not classified (Lack of data)
	pH: 2,5 – 3,5
Serious eye damage/irritation	: Not classified (Technical impossibility to obtain the data. May cause eye irritation)
	pH: 2,5 – 3,5
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Further details: Acute toxicity)
STOT-single exposure	: Not classified (Technical impossibility to obtain the data. May cause respiratory irritation.
STOT-repeated exposure	: Not classified (Further details: Acute toxicity)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information		
12.1. Toxicity		
Ecology - general : Hazardous to the aquatic environment, short-term : (acute) Hazardous to the aquatic environment, long-term : (chronic)	Presents no specific risk for the environment. Not classified Not classified	
Aescin		
EC50 - Crustacea [1]	59 mg/l (24h)	
12.2. Persistence and degradability		
No additional information available		
12.3. Bioaccumulative potential		
No additional information available		
12.4. Mobility in soil		
No additional information available		
12.5. Results of PBT and vPvB assessment		
No additional information available		
12.6. Endocrine disrupting properties		
No additional information available		
12.7. Other adverse effects		
No additional information available		

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

ADR	IMDG	ΙΑΤΑ
4.1. UN number or ID number	· · ·	
Not applicable	Not applicable	Not applicable
4.2. UN proper shipping name	· · · ·	
Not applicable	Not applicable	Not applicable
4.3. Transport hazard class(es)		
Not applicable	Not applicable	Not applicable
I.4. Packing group	· · ·	
Not applicable	Not applicable	Not applicable
4.5. Environmental hazards	· · · ·	
Not applicable	Not applicable	Not applicable

14.6. Special precautions for user

Overland transport Not applicable

Transport by sea Not applicable

Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

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POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

	Full text of H- and EUH-statements:
I	

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.