

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

1.1. Product identifier

Product form	: Substance
Substance name	: Artemether RS
Chemical name	: Artemether
CAS-No.	: 71963-77-4
Product code	: 201600063

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

Relevant identified uses

Use of the substance/mixture	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals

Uses advised against

Restrictions on use	: Not for food, drug or home use
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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
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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]

Organic Peroxides, Type E	H242
Reproductive toxicity, Category 2	H361d
Full text of H- and EUH-statements: see section 16	

Adverse physicochemical, human health and environmental effects

Suspected of damaging the unborn child. Heating may cause a fire.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS02

GHS08

Signal word (CLP)	: Warning
Hazard statements (CLP)	: H242 - Heating may cause a fire. H361d - Suspected of damaging the unborn child.
Precautionary statements (CLP)	: P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

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No smoking.
P234 - Keep only in original packaging.
P240 - Ground and bond container and receiving equipment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P370+P378 - In case of fire: Use media other than water to extinguish.
P405 - Store locked up.
P410 - Protect from sunlight.
P411 - Store at temperatures not exceeding .
P420 - Store separately.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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

Hazard pictograms (CLP) :



GHS08

2.3. Other hazards

Other information : Active substance (in pharmaceutical products).
Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Artemether	CAS-No.: 71963-77-4	≤ 100	Org. Perox. E, H242 Repr. 2, H361d

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

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

No additional information available

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

No additional information available

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SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Absorb with an inert material and place in an appropriate waste disposal container.
- Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Do not expose pregnant or breastfeeding women.
- Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.
- Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
- Packaging materials : Keep in original containers.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Colourless. white.
Appearance	: Crystalline powder. Needles.
Molecular mass	: 298.38 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: ≈ 87 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Heating may cause a fire.
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: < 0.1 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 4.4
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

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9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

Heating may cause a fire.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met; Expert judgement and weight of evidence determination)
Acute toxicity (dermal)	: Not classified (Lack of data; Expert judgement and weight of evidence determination)
Acute toxicity (inhalation)	: Not classified (Lack of data; Expert judgement and weight of evidence determination)

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LD50 oral rat	> 2000 mg/kg (estimated value)
Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Suspected of damaging the unborn child.
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Inconclusive data)
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Lack of data)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Lack of data)

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12.2. Persistence and degradability

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Persistence and degradability	Not rapidly degradable
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12.3. Bioaccumulative potential

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Partition coefficient n-octanol/water (Log Pow)	4.4
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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




SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 3108	UN 3108	UN 3108
14.2. UN proper shipping name		
ORGANIC PEROXIDE TYPE E, SOLID	ORGANIC PEROXIDE TYPE E, SOLID	Organic peroxide type E, solid
Transport document description		
UN 3108 ORGANIC PEROXIDE TYPE E, SOLID, 5.2, (D)	UN 3108 ORGANIC PEROXIDE TYPE E, SOLID, 5.2	UN 3108 Organic peroxide type E, solid, 5.2
14.3. Transport hazard class(es)		
5.2	5.2	5.2
		
14.4. Packing group		
Not applicable	Not applicable	Not applicable

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ADR	IMDG	IATA
14.5. Environmental hazards		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-J EmS-No. (Spillage): S-R	Dangerous for the environment: No
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: P1
Special provisions (ADR)	: 122, 274
Limited quantities (ADR)	: 500g
Excepted quantities (ADR)	: E0
Packing instructions (ADR)	: P520
Mixed packing provisions (ADR)	: MP4
Transport category (ADR)	: 2
Special provisions for carriage - Packages (ADR)	: V1
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV15, CV22, CV24, CV29
Tunnel restriction code (ADR)	: D

Transport by sea

Special provisions (IMDG)	: 122, 274
Limited quantities (IMDG)	: 500 g
Excepted quantities (IMDG)	: E0
Packing instructions (IMDG)	: P520
Stowage category (IMDG)	: D
Stowage and handling (IMDG)	: SW1
Segregation (IMDG)	: SG35, SG36, SG72
Properties and observations (IMDG)	: Decomposes at elevated temperatures or in a fire. Burns vigorously. Insoluble in water. Contact with the eyes and skin should be avoided. May evolve irritant or toxic fumes.

Air transport

PCA Excepted quantities (IATA)	: E0
PCA Limited quantities (IATA)	: Forbidden
PCA limited quantity max net quantity (IATA)	: Forbidden
PCA packing instructions (IATA)	: 570
PCA max net quantity (IATA)	: 10kg
CAO packing instructions (IATA)	: 570
CAO max net quantity (IATA)	: 25kg
Special provisions (IATA)	: A20, A802
ERG code (IATA)	: 5L

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

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)

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REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (1005/2009)

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

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

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)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	ERG code (IATA)	Added
	Special provisions (IATA)	Added
	CAO max net quantity (IATA)	Added
	CAO packing instructions (IATA)	Added
	PCA max net quantity (IATA)	Added
	PCA packing instructions (IATA)	Added
	PCA limited quantity max net quantity (IATA)	Added
	PCA Limited quantities (IATA)	Added
	PCA Excepted quantities (IATA)	Added
	Danger labels (IATA)	Added
	Proper Shipping Name (IATA)	Added
	Properties and observations (IMDG)	Added
	Proper Shipping Name (IMDG)	Added
	Danger labels (IMDG)	Added
	EmS-No. (Spillage)	Added
	EmS-No. (Fire)	Added
	Limited quantities (IMDG)	Added
	Segregation (IMDG)	Added
	Stowage and handling (IMDG)	Added
	Stowage category (IMDG)	Added
	Excepted quantities (IMDG)	Added
	Special provisions (IMDG)	Added
	Special provisions for carriage - Operation (ADR)	Added

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Indication of changes		
Section	Changed item	Comments
	Special provisions for carriage - Loading, unloading and handling (ADR)	Added
	Special provisions for carriage - Packages (ADR)	Added
	Mixed packing provisions (ADR)	Added
	Packing instructions (ADR)	Added
	Supersedes version of	Added
	Revision date	Added
1.1	CAS-No.	Added
1.1	Synonyms	Removed
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.2	Hazard statements (CLP)	Modified
2.2	Signal word (CLP)	Modified
2.2	Hazard pictograms (CLP)	Modified
2.2	Precautionary statements (CLP)	Modified
2.3	Other information	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after inhalation	Modified
4.1	First-aid measures after ingestion	Modified
4.1	First-aid measures after eye contact	Modified
4.2	Symptoms/effects	Removed
4.2	Symptoms/effects after ingestion	Removed
4.2	Symptoms/effects after skin contact	Removed
4.2	Symptoms/effects after inhalation	Removed
4.2	Symptoms/effects after eye contact	Removed
4.3	Other medical advice or treatment	Removed
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Fire hazard	Removed
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified

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Indication of changes		
Section	Changed item	Comments
6.1	Protective equipment	Added
6.1	Emergency procedures	Modified
6.1	General measures	Modified
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Modified
6.4	Reference to other sections (8, 13)	Added
7.1	Additional hazards when processed	Modified
7.1	Precautions for safe handling	Modified
7.1	Hygiene measures	Modified
7.2	Packaging materials	Added
7.2	Technical measures	Removed
7.2	Storage conditions	Modified
7.3	Specific end uses	Removed
8.2	Respiratory protection	Modified
8.2	Hand protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Eye protection	Modified
8.2	Skin and body protection	Modified
9	Flammability	Added
9	Odour	Removed
9	Melting point	Added
9	Solubility in water	Modified
9	Molecular mass	Added
9	Colour	Added
9	Appearance	Modified
10.1	Reactivity	Removed
10.3	Possibility of hazardous reactions	Added
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	LD50 oral rat	Added
11.1	ATE CLP (oral)	Removed
12.1	Ecology - general	Removed
13.1	Regional waste regulation	Removed
14.1	UN-No. (ADR)	Added
14.1	UN-No. (IMDG)	Added
14.1	UN-No. (IATA)	Added
14.2	Proper Shipping Name (ADR)	Added

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Indication of changes		
Section	Changed item	Comments
14.3	Danger labels (ADR)	Added
14.3	Class (ADR)	Added
14.6	Packing instructions (IMDG)	Added
14.6	Transport category (ADR)	Added
14.6	Special provisions (ADR)	Added
14.6	Excepted quantities (ADR)	Added
14.6	Limited quantities (ADR)	Added
14.6	Tunnel restriction code (ADR)	Added
14.6	Classification code (ADR)	Added

Full text of H- and EUH-statements:	
H242	Heating may cause a fire.
H361d	Suspected of damaging the unborn child.
Org. Perox. E	Organic Peroxides, Type E
Repr. 2	Reproductive toxicity, Category 2

Safety Data Sheet (SDS), EU

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