

AMPLIRUN® TREPONEMA PALLIDUM DNA CONTROL

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Edition: 3. Date: 09/02/2023



AMPLIRUN® CONTROL REAGENT includes several mixtures, which have all been evaluated for classification, according to Regulation (EC) No. 1272/2008 [CLP].

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

1.1. Product identifier

| | |
|--------------|--|
| Product form | : Mixture |
| Product name | : AMPLIRUN® TREPONEMA PALLIDUM DNA CONTROL |
| Trade name | : AMPLIRUN® CONTROL REAGENT |
| Product code | : MBC109 |

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

1.2.1. Relevant identified uses

Use of the substance/mixture : *In Vitro* Diagnostic use.

1.2.2. Uses advised against

Restrictions on use : No additional information available.

1.3. Details of the supplier of the safety data sheet

VIRCELL, S.L.

Parque Tecnológico de la Salud, Avicena 8

18016 Granada - Spain

T +34 958-44 12 64 - F +34 958-51 07 12

customerservice@vircell.com

1.4. Emergency telephone number

Emergency number : 112 (24 hour service) – applicable to EU countries only.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified.

Adverse physicochemical, human health and environmental effects

No additional information available.

2.2. Label elements

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

No labelling applicable.

2.3. Other hazards

Other hazards which do not result in classification : Reagents should be considered as potentially infectious and handled accordingly.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II.

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|---|
| First-aid measures general | : Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. If medical advice is needed, have product container or label at hand. |
| First-aid measures after inhalation | : Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of breathing difficulties administer oxygen. If you feel unwell, seek medical advice. |
| First-aid measures after skin contact | : After contact with skin: Take off immediately all contaminated clothing, and wash immediately with plenty of water and soap. If skin irritation occurs: Get medical advice/attention. |
| First-aid measures after eye contact | : If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention if ill effect or irritation develops. |
| First-aid measures after ingestion | : If swallowed: Rinse mouth with water (only if the person is conscious). Do not induce vomiting. Never give anything by mouth to an unconscious person. Consult a doctor/medical service if you feel unwell. |

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

| | |
|-------------------------------------|----------------------------------|
| Symptoms/effects after skin contact | : May cause moderate irritation. |
| Symptoms/effects after eye contact | : May cause moderate irritation. |

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 : Water, carbon dioxide (CO₂), dry chemical powder, foam.

Unsuitable extinguishing media : No additional information available.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No additional information available.

Explosion hazard : No additional information available.

5.3. Advice for firefighters

Precautionary measures fire : Evacuate the personnel away from the fumes.

Protective equipment for firefighters : Extra personal protection: complete protective clothing including self-contained breathing apparatus.

Other information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Alert emergency personnel.

6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye/face protection. Avoid breathing dust/fume/gas/mist/vapours/spray.

Emergency procedures : Evacuate unnecessary personnel. Ensure adequate ventilation, especially in confined areas.

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 : Stop leak if safe to do so.

Methods for cleaning up : Ventilate affected area. Wear personal protection equipment. Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Wash with plenty of soap and water. Consult the appropriate authorities about waste disposal.

Other information : Do not allow uncontrolled discharge of product into the environment.

6.4. Reference to other sections

For disposal of residues refer to section 13 : Disposal considerations. For further information refer to section 8: Exposure controls/personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes.

Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.

Storage conditions : Keep container tightly closed. Store in a well-ventilated place. Keep cool.

Heat and ignition sources : Keep away from open flames, hot surfaces and sources of ignition.

7.3. Specific end use(s)

In Vitro Diagnostic use. Use the product in compliance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available.

8.2. Exposure controls

Appropriate engineering controls:

Provide adequate ventilation.

Personal protective equipment:

Gloves. Protective goggles. Protective clothing.

Hand protection:

Wear suitable gloves tested to EN 374.

Eye protection:

Chemical goggles or safety glasses.

Skin and body protection:

Use chemically protective clothing. Lab coat.

Respiratory protection:

Not required for normal conditions of use.

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Personal protective equipment symbol(s):



Environmental exposure controls:

Do not allow into drains or water courses.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|--|-------------------|
| Physical state | : Not determined. |
| Colour | : Not determined. |
| Odour | : Not determined. |
| Odour threshold | : Not determined. |
| pH | : Not determined. |
| Relative evaporation rate (butylacetate=1) | : Not determined. |
| Melting point | : Not determined. |
| Freezing point | : Not determined. |
| Boiling point | : Not determined. |
| Flash point | : Not determined. |
| Auto-ignition temperature | : Not determined. |
| Decomposition temperature | : Not determined. |
| Flammability (solid, gas) | : Not determined. |
| Vapour pressure | : Not determined. |
| Relative vapour density at 20 °C | : Not determined. |
| Relative density | : Not determined. |
| Solubility | : Not determined. |
| Log Pow | : Not determined. |
| Viscosity, kinematic | : Not determined. |
| Viscosity, dynamic | : Not determined. |
| Explosive properties | : Not determined. |
| Oxidising properties | : Not determined. |
| Explosive limits | : Not determined. |
| Particle characteristics | : Not applicable. |

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

No additional information available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No polymerization. No dangerous reactions known under normal conditions of use.

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.

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SECTION 11: Toxicological information

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

| | |
|-----------------------------------|-------------------|
| Acute toxicity (oral) | : Not classified. |
| Acute toxicity (dermal) | : Not classified. |
| Acute toxicity (inhalation) | : Not classified. |
| Skin corrosion/irritation | : Not classified. |
| Serious eye damage/irritation | : Not classified. |
| Respiratory or skin sensitisation | : Not classified. |
| Germ cell mutagenicity | : Not classified. |
| Carcinogenicity | : Not classified. |
| Reproductive toxicity | : Not classified. |
| STOT-single exposure | : Not classified. |
| STOT-repeated exposure | : Not classified. |
| Aspiration hazard | : Not classified. |

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

| | |
|--|--|
| Adverse health effects caused by endocrine disrupting properties | : The mixture does not contain substance(s) included in the list established in accordance with Article 59 (1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %. |
|--|--|

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

| | |
|--------------------------|-------------------|
| Acute aquatic toxicity | : Not classified. |
| Chronic aquatic toxicity | : Not classified. |

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

| | |
|--|--|
| Adverse effects on the environment caused by endocrine disrupting properties | : The mixture does not contain substance(s) included in the list established in accordance with Article 59 (1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %. |
|--|--|

12.7. Other adverse effects

No additional information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|-------------------------|---|
| Waste treatment methods | : Consult the appropriate local waste disposal expert about waste disposal. |
|-------------------------|---|

SECTION 14: Transport information

In accordance with ADN / ADR / IATA / IMDG / RID

| ADR | IMDG | IATA | ADN | RID |
|-------------------------------------|----------------|----------------|----------------|----------------|
| 14.1. UN number or ID number | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

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| 14.2. UN proper shipping name | | | | |
|----------------------------------|----------------|----------------|----------------|----------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.4. Packing group | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.5. Environmental hazards | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

No additional information available.

14.6. Special precautions for user

Overland transport

Not applicable.

Transport by sea

Not applicable.

Air transport

Not applicable.

Inland waterway transport

Not applicable.

Rail 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

Contains no REACH substances with Annex XVII restrictions.

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 1, slightly hazardous to water (Classification according to AwSV, Annex 1).

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance).

15.2. Chemical safety assessment

No additional information available.

SECTION 16: Other information

| Abbreviations and acronyms: | |
|-----------------------------|---|
| SDS | Safety Data Sheet |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| IMDG | International Maritime Dangerous Goods |
| IATA | International Air Transport Association |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| vPvB | Very Persistent and Very Bioaccumulative |
| PBT | Persistent Bioaccumulative Toxic |

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| | |
|-----|---|
| CAS | CAS (Chemical Abstracts Service) number |
| CSR | CSR - Chemical Safety Report |

Other information : This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product. It is the user's responsibility to take mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product.

SDS EU (REACH Annex II)

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