



## CLART<sup>®</sup> Septibac

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*"This document and the information contained herein are provided solely for the purpose of complying with the requirements of Regulation 1272/2008/EC, Regulation 1907/2009/EC (REACH) and other applicable regulations.*

*"GENOMICA assumes no liability for damage to property and / or injury resulting from use and contact with this product"*

Date: 11/11/2021

**Drafted by:**

Ana Romera

QARA Senior Specialist

Date: 11/11/2021

**Reviewed by:**

Ascensión Hernández

QARA Manager

Date: 11/11/2021

**Approved by:**

Nuria Manjón

Technical Director

## 1. Identification of the substance/preparation and the company/undertaking

### 1.1. Product identifiers

**Product name:**

CLART® Septibac

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

*Characterization of microorganisms causing sepsis via genomic identification for in vitro diagnostics*

### 1.3 Details of the supplier

**Company:**

GENOMICA S.A.U.

Parque Empresarial Alvento. Edificio B

Calle Vía de los Poblados, 1 - 1ª planta

28033 Madrid

Phone: 34-91 674 89 90 Fax: 34-91 67489 91

E-mail address: [nmanjon@genomica.com](mailto:nmanjon@genomica.com)

### 1.4 Emergency telephone number: 112 (EU)

## 2. Classification and Hazards identification

### 2.1 Classification of the mixture

Classification according to the [Regulation \(EC\) No 1272/2008](#); is a mixer of substances

### 2.2 . Hazards identification

- **Serious eye damage/eye irritation**
- **Hazardous to the aquatic environment**
- **Carcinogenicity**
- **Toxicity**
- **Skin corrosion/irritation**
- **Specific target organ toxicity single**
- **Respiratory sensibilisation**

**Principle routes of exposure:** Ingestion, skin and eye contact and inhalation.

**Ingestion:** May cause gastrointestinal irritation.

**Skin contact:** There is no health hazard if skin contact is to occur.

**Eye contact:** May cause eye mucose irritation.

**Inhalation:** May cause irritation of respiratory tract.

For pictograms and hazard statements see Table in section 3

### 2.3. Other Hazards

The present substance/preparation does not contain components that might be considered bioaccumulative or persistent toxins, or very accumulative or very persistent at a level of 0.1% or higher.

Concentration of the potentially dangerous components according to Regulation is below the permitted limits.

## MATERIAL SAFETY DATA SHEET (MSDS)

Prepared according to 1272/2008/EC and 1907/2009/EC

### 3. Composition/ information on ingredients

Dangerous components according to Regulation No 1272/2008/EC.



#### AMPLIFICATION REAGENTS

| COMPONENTS       | %     | Classification   |
|------------------|-------|--|
| PCR Master Mix   | 80-90 | <i>This product is a mixture of substances.</i><br><b>It does not contain any dangerous components</b> |
| Oligonucleotides | 20-10 | <i>This product is a mixture of substances.</i><br><b>It does not contain any dangerous components</b> |

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### DETECTION REAGENTS


| HYBRIDISATION SOLUTION (SH)                               | %    | Classification   | Pictogram, Signal Word Code(s)*  | Hazard statement Code(s)*                              |
|---|------|--|--|--|
| Sodium phosphate  | 25   | <i>This product is a mixture of substances.</i><br><b>It does not contain any dangerous components</b>   |  |  |
| SSC   | 5    | <i>This product is a mixture of substances.</i><br><b>It does not contain any dangerous components</b>   |  |  |
| EDTA<br>CAS. No: 10378-23-1<br>EC-No 10378-23-1 200-573-9 | 0.2  | <ul style="list-style-type: none"> <li>- <b>Acute Toxicity (category 4)</b></li> <li>- <b>Eye Damage (Category 1)</b></li> </ul> Concentration of the potentially dangerous components according to Regulation is below the permitted limits.  | Danger!<br>   | H302, H318   |
| Triton X-100  | 2.25 | <i>This product is a mixture of substances.</i><br><b>Dangerous components:</b><br><b>p-tertiary-Octylphenoxy polyethyl alcohol</b> CAS-No.: 9002-93-1<br><b>concentration &lt;0.05</b> <ul style="list-style-type: none"> <li>- <b>Serious eye damage (Category 1)</b></li> <li>- <b>Chronic aquatic toxicity (Category 3)</b></li> </ul> | Danger!<br> | H302, H315, H318, H400, H410<br>P280, P305, P351, P338 |

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|  |  |   |  |  |
|--|--|---|--|--|
|  |  | <p>Concentration of the potentially dangerous components according to Regulation is below the permitted limits.</p> |  |  |
|--|--|---|--|--|

For the full text of the H and P-Statements mentioned in this Section, see Section 16.  
\*Only for dangerous components

| RE (Developer):<br>Hazardous components**   | Classification   | Pictogram, Signal<br>Word Code(s) *   | Hazard statement<br>Code(s) * |
|---|--|---|-------------------------------|
| <p><b>3,3'-dimethoxybenzidine</b>    o-</p> <p><b>dianisidine</b></p> <p>CAS-No.: 119-90-4<br/>EC-No. : 204-355-4</p> | <p>According to Regulation No 1272/2008. this substance is classified as:</p> <ul style="list-style-type: none"> <li>- <b>Acute Toxicity (Category 4)</b></li> <li>- <b>Carcinogens (Category 1B)</b></li> </ul> <p>Concentration of the potentially dangerous components according to Regulation is below the permitted limits.</p> | <p>Danger!</p>  | <p>H302, H350</p>             |

## MATERIAL SAFETY DATA SHEET (MSDS)

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|  |  |   |  |
|--|--|---|--|
| <p><b>Hydrogen peroxide</b><br/>CAS-No.: 7722-84-1<br/>EC-No.: 231-765-0</p> | <p>According to Regulation No 1272/2008.<br/>this substance is classified as:</p> <ul style="list-style-type: none"> <li>- <b>Acute toxicity, Oral (Category 4)</b></li> <li>- <b>Serious eye damage (Category 1)</b></li> </ul> <p>Concentration of the potentially dangerous components according to Regulation is below the permitted limits.</p> | <p>Danger!</p> <div style="text-align: center;">  </div> | <p style="text-align: center;">H302,H318</p> |
|--|--|---|--|

For the full text of the H-Statements mentioned in this Section, see Section 16.

\*Only for dangerous components

\*\*Composition not available

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| DC (Conjugate Diluent).     | %   | Classification  |
|-----------------------------|-----|---|
| BSA saline phosphate buffer | 100 | This product is a mixture of substances.<br>Does not contain dangerous components |

| CJ (Conjugate Solution). | %  | Classification  |
|--------------------------|----|---|
| Streptavidin peroxidase  | 1  | This product is a mixture of substances.<br>Does not contain dangerous components |
| DC (Conjugate Diluent)   | 99 | This product is a mixture of substances.<br>Does not contain dangerous components |

| TL (Wash Buffer).                     | %   | Classification  |
|---------------------------------------|-----|---|
| Saline phosphate buffer<br>With Tween | 100 | This product is a mixture of substances.<br>Does not contain dangerous components |



#### 4. First Aid Measures

**General advice.** Consult a physician. Show this safety data sheet to the doctor in attendance.

**If inhaled**

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

**In case of skin contact**

Wash off with soap and plenty of water. Consult a physician.

**In case of eye contact**

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

**If swallowed**

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

No data available

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

No data available

#### 5. FIRE-fighting measures

**5.1 Extinguishing media**

Suitable extinguishing media.

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

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

Flammable. Keep away from sources of ignition. It may form explosive mixtures with air.

In case of fire toxic vapours, e.g. Carbon oxides, nitric oxide, carbon monoxide, can be released.

**5.3 Advice for firefighters**

Wear self-contained breathing apparatus for firefighting if necessary.

**5.4 Further information**

No data available

#### 6. Accidental Release Measures

**6.1 Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas

**6.2 Environmental precautions**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

**6.3 Methods for cleaning up**

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

**7. Handling and Storage****7.1 Precautions for safe handling**

Use personal protective equipment. Protect from contaminations by using a laminar flow cabin.

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

Store reagents at the temperatures indicated in the handbook and in the reagent's label.

**8.1. Control parameters**

Components with workplace control parameters

By using the product according with the requirements, no air pollution is expected

**8.2 Personal protective equipment**

**Hand protection:** Wear protective gloves to prevent skin contact.

**Body protection:** Wear lab coat.

**Eye protection:** Wear protective glasses.

**Hygiene measures:** Keep away from food and drink. Wash hands before breaks and at the end of the workday.

**8.3 Environmental exposure controls**

Keep away from drains. Avoid contamination of water or soil.

**9. Physical and chemical properties**

No data available.

**10. Stability and Reactivity****10.1 Reactivity**

No data available

**10.2 Chemical stability**

Stable under recommended storage conditions.

**10.3 Possibility of hazardous reactions**

No data available

**10.4 Conditions to avoid**

No data available

**10.5 Incompatible materials**

No data available

**10.6 Hazardous decomposition products**

Other decomposition products - no data available

**11. Toxicological information****11.1 Acute toxicity**

The mixture is not classified to be hazardous (see chapter 15.1).

*Acute toxicity of the hybridisation solution*

- EDTA: LD50 Oral - rat - 630 - 1.260 mg/kg

**11.2 Skin Corrosion/Irritation****11.3 Serious Eye Damage/Irritation****11.4 Respiratory Or Skin Sensitization****11.5 Germ Cell Mutagenicity**

No information available

**11.6 Carcinogenicity**

IARC: no components of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen By IARC.

**11.7 Reproductive Toxicity**

No information available

**11.8 STOT-Single Exposure**

No specific target organ toxicant because no component is known as specific target organ toxicant.  
STOT-repeated exposure

No specific target organ toxicant because no component is known as specific target organ toxicant.

**11.9 Aspiration Hazard**

No information available

**12. Ecological information****12.1 Acute aquatic toxicity**

The mixture is not classified to be toxic to water organisms.

*Acute aquatic toxicity of the developer*

- The mixture is not classified to be toxic to water organisms, calculated L(E)C > 100 mg/l .

*Acute aquatic toxicity of the hybridization solution*

- The mixture is not classified to be toxic to water organisms Category 3

**12.2 Persistence and Degradability**

No data available.

**12.3 Bioaccumulative Potential**

No data available.

**12.4 Mobility in Soil**

No data available.

**12.5 Results Of Pbt And Vpvt Assessment**

None of the components is listed as PBT or vPvB relevant.

**12.6 Other Adverse Effects**

If used appropriately, no ecological problems are to be expected.

**13. Disposal considerations**

Waste disposal must be in accordance with appropriate state and local regulations.  
Waste (with exception of the biological residues) can normally be disposed with normal waste.

**14. Transport information**

Shipment is not subject to any norm, as the product is not considered hazardous.

**14.1 Un Number**

ADR/RID: -      IMDG: -      IATA: -

**14.2 Un Proper Shipping Name**

ADR/RID: No dangerous goods    IMDG: No dangerous goods    IATA: No dangerous goods

**14.3 Transport Hazard Class(Es).**

ADR/RID: -      IMDG: -      IATA: -

**14.4 Packing Group:**

ADR/RID:-      IMDG: -    IATA: -

**14.5 Environmental Hazards:** No Data Available.

**14.6 Special Precautions For User:** No Data Available.

**15. Regulatory information**

**THE MATERIAL SAFETY DATA SHEET (MSDS) IS PREPARED ACCORDING TO**

**Regulation (EC) No 1272/2008** of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

**16. Other information****16.1 Fully text to the H-Sentences mentioned:****H (Hazard)-statements**

H302 Harmful if swallowed.

H315 Causes skin irritation

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

H350 May cause cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

**P (Precautionary)-statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**16.2 Categories of the Acute Toxicity (ATE) according EC 1272/2008:**

Further information: The information stated above is based on our actual knowledge and is intended to describe our products concerning safety recommendations. The information does not assure product properties and is therefore no basis for legal action. The REACH registration numbers in heading 3 is available only after a registration by the REACH Agency. Or it is not available as the substances or its use is exempted from registration according to article 2 REACH Regulation EC 1907/2006, or the annual tonnage does not require a registration is envisaged for a later registration deadline.