NOTE:

GENOMICA provides safety data sheet only for the hazardous components of the KIT CLART® PNEUMOVIR

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

Prepared according to 1907/2006/EC,
Rev.7: 01.09.15
1. Identification of the substance/preparation and the company/undertaking

1.1. Product identifiers

**Product name:** CLART®PNUEMOVIR

1.2 Relevant identified uses of the mixture and uses advised against

*Characterization of viruses causing human respiratory infections via genomic identification for in vitro diagnosis*

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: srueda@genomica.com

**1.4 Emergency telephone number:** 112 (EU)
2.1 Classification of the mixture

Classification according to the Regulation (EC) No 1272/2008 is not applicable.

According to the Article 1 point 5. d) -This Regulation shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC.


Classification according to the Regulation 67/548/EC , directive 1999/45/EC and Regulations 1907/2006/EC

According to the Regulation 67/548/EC , directive 1999/45/EC and Regulations 1907/2006/EC the product CLART®PNUEMOVIR does not require a Material Safety Data Sheet as it contains a quantity not exceeding 1% of components classified as dangerous and not greater than 0.1% of components classified as carcinogenic.

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 sensitisation

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.
### 3. Composition/ information on ingredients

Dangerous components according to 67/548/EWG, 1999/45/EG and Regulation No 1272/2008.

*Regulation No 1272/2008 shall apply if the intended use is different from in vitro diagnostic medical device under the Directive Directive 98/79/EC.*

<table>
<thead>
<tr>
<th>SEML</th>
<th>Hazardous components</th>
<th>Classification</th>
<th>Pictogram, Signal Word Code(s)</th>
<th>Hazard statement Code(s)</th>
</tr>
</thead>
</table>
| Guanidine thiocyanate | CAS-No: 593-84-0  
EC-No: 209-812-1  
Index-No: 615-030-00-5 |  
According to 67/548/EWG, 1999/45/EG this substance is classified as:  
Harmful by inhalation, in contact with skin and if swallowed. Contact with acids liberates very toxic gas. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Causes burns.  
According to Regulation No 1272/2008. this substance is classified as:  
- Acute toxicity, Oral (Category 4)  
- Acute toxicity, Inhalation (Category 4)  
- Acute toxicity, Dermal (Category 4)  
- Skin corrosion (Category 1C)  
- Chronic aquatic toxicity (Category 3) | Danger! | R20/21/22,R32,R34,R52/53 |
<p>|  |  |  |  | H302 + H312 + H332, H314,H412 |</p>
<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Classification</th>
<th>Warning</th>
<th>R-Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Lauroylsarcosine sodium salt</td>
<td>137-16-6</td>
<td>According to 67/548/EWG, 1999/45/EG, this substance is classified as:</td>
<td></td>
<td>R23, R38, R41</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- T: Toxic</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Xi: Irritant</td>
<td></td>
<td>H315, H318, H330</td>
</tr>
<tr>
<td></td>
<td></td>
<td>According to Regulation No 1272/2008, this substance is classified as:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Acute toxicity, Inhalation (Category 2),</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Skin irritation (Category 2),</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Serious eye damage (Category 1),</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DL-Dithiothreitol</td>
<td>3483-12-3</td>
<td>According to 67/548/EWG, 1999/45/EG, this substance is classified as:</td>
<td></td>
<td>R22 - R36/37/38</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Xn Harmful</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>According to Regulation No 1272/2008, this substance is classified as:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Acute toxicity, Oral (Category 4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Skin irritation (Category 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Eye irritation (Category 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Specific target organ toxicity single exposure (Category 3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Warning</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>R22, R36/37/38</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>H302, H315, H319, H335</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## ISOPROPA NOL

**Classification**

According to 67/548/EWG, 1999/45/EC this substance is classified as:
- **highly flammable**: F
- **irritant**: Xi;

According to Regulation No 1272/2008, this substance is classified as:
- Flammable liquid (Category 2),
- Eye irritation (Category 2),
- Stot SE3*

**Pictogram, Signal Word Code(s)**

- Warning!

<table>
<thead>
<tr>
<th>Hazard statement Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R11, R36, R67</td>
</tr>
<tr>
<td>H225, H319, H336</td>
</tr>
</tbody>
</table>

---

## SH (Hybridisation solution)

**Hazardous components**

**Etilendiamina-tetraacetato de tetrasodio dihidrato**

- CAS. No : 10378-23-1
- EC-No 10378-23-1 200-573-9

**Classification**

According to 67/548/EWG, 1999/45/EG this substance is classified as:
- **Xn**: Harmful
- **Xi**: Irritant

According to Regulation No 1272/2008, this substance is classified as:
- Acute Toxicity (category 4)
- Eye Damage (Category 1)

**Pictogram, Signal Word Code(s)**

- Danger!

<table>
<thead>
<tr>
<th>Hazard statement Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R22, R41</td>
</tr>
<tr>
<td>H302, H318</td>
</tr>
</tbody>
</table>
Triton X-100 solution
p-tertiary-Octylphenoxypolyethyl alcohol
CAS-No.: 9002-93-1

According to 67/548/EWG, 1999/45/EG this substance is classified as:
- Xi: Irritant

According to Regulation No 1272/2008 this substance is classified as:
- Serious eye damage (category 1)
- Chronic aquatic toxicity (category 3)

---

RE (Developer):
Hazardous components

<table>
<thead>
<tr>
<th>Substance</th>
<th>Classification</th>
<th>Pictogram, Signal Word Code(s)</th>
<th>Hazard statement Code(s)</th>
</tr>
</thead>
</table>
| 3,3’-dimethoxybenzidine o-dianisidine | According to EU Directives 67/548/EEC or 1999/45/EC this substance is classified as:  
- Xn: Harmful | Danger! | R22, R45, H302, H350 |
| | According to Regulation No 1272/2008 this substance is classified as:  
- Acute Toxicity (category 4)  
- Carcinogens (category 1B) |  |  |
| Citric acid monohydrate | According to EU Directives 67/548/EEC or 1999/45/EC this substance is classified as:  
- Xi: Irritant | Warning! | R36, H319 |
## 5-Chloro-2-methyl-4-isothiazolin-3-one
**CAS-No.:** 26172-55-4  
**EC-No.:** 247-500-7

According to 67/548/EWG, 1999/45/EG, this substance is classified as:
- **Xn:** Harmful
- **C:** Corrosive

According to Regulation No 1272/2008, this substance is classified as:
- Skin corrosion (Category 1B)
- Respiratory sensitisation (Category 1)
- Skin sensitisation (Category 1)

---

## 2-Methyl-2H-isothiazol-3-one
**CAS-No.:** 2682-20-4  
**EC-No.:** 220-239-6

According to EU Directives 67/548/EEC or 1999/45/EC, this substance is classified as:
- **Xi:** Irritant
- **T:** Toxic
- **N:** Dangerous for the environment

According to Regulation (EC) No 1272/2008, this substance is classified as:
- Acute toxicity Oral (Category 4)
- Acute toxicity Inhalation (Category 3)
- Skin corrosion (Category 1B)
- Skin sensitisation (Category 1)
- Specific target organ toxicity - single exposure (Category 3) Respiratory system
- Acute aquatic toxicity (Category 1)
**OPTIONAL MATERIAL SAFETY DATA SHEET (MSDS)**

Prepared according to 1907/2006/EC.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Classification</th>
<th>H-Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>hydrogen peroxide</td>
<td>According to EU Directives 67/548/EEC or 1999/45/EC this substance is classified as:</td>
<td>R22,R41,</td>
</tr>
<tr>
<td></td>
<td>- Xn: Harmful</td>
<td>H302,H318,</td>
</tr>
<tr>
<td></td>
<td>- Xi: Irritant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>According to Regulation No 1272/2008 this substance is classified as:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Acute toxicity, Oral (Category 4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Serious eye damage (Category 1)</td>
<td></td>
</tr>
</tbody>
</table>

For the full text of the H-Statements mentioned in this Section, see Section 16.
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. FİRE-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 fire fighting 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 vapours, 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. Exposure controls/Personal protection

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.
Protección de los ojos: None.
Higiene 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 SEML
- Guanidine Thiocyanate: LD50 Oral - rat - 593mg/kg, LD50 Intraperitoneal –mouse-300mg/kg
- DL-Dithiothreitol : LD50 Oral-rat- 400mg/kg
- N-laurolsacosine sodium salt: LD50 Oral-rat-male and female >5.000 mg/kg ( OECD Test guideline 401)

Acute toxicity of the Isoporpanol
- LD50 Oral - rat :>2000 mg/kg, LD50 Inhalation –rat:>=20 mg/kg,

Acute toxicity y of the hybridisation solution
- EDTA: LD50 Oral - rat - 630 - 1.260 mg/kg

11.2 Skin Corrosion/Irritation

N-laurolsacosine sodium salt: skin rabbit –result irritating to skin .
Isoporpanol: LD50 skin rabbit :>2000mg/kg.

11.3 Serious Eye Damage/Irritation

N-laurolsacosine sodium salt: eyes-rabbit–result: Risk of serious damage to eyes . ( OECD Test guideline 401)

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 SEML
- Toxicity to daphnia
- Toxicity to aquatic invertebrates
- Toxicity to algae
- Toxicity to fish
- Toxicity to bacteria

Acute aquatic toxicity of the Isopropanol
- Toxicity to daphnia
- Toxicity to algae
- Toxicity to fish

Acute aquatic toxicity of the developer
- The mixture is not classified to be toxic to water organisms, calculated L(E)C > 100 mg/l (see chapter 15.1).

Acute aquatic toxicity of the hybridisation 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 Vpvb 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

Shipmet 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

16. Other information

16.1 Fully text to the R-Phrases mentioned
R36/37/38 - Irritating to eyes, respiratory system and skin.
R22 Harmful if swallowed.
R23 Toxic by inhalation.
R34 Causes burns.
R36 Irritating to eyes.
R37 Irritating to respiratory system.
R41 Risk of serious damage to eyes.
R43 May cause sensitisation by skin contact.
R50 Very toxic to aquatic organisms.
R52/53 Harmful to aquatic organisms, may cause long term adverse affects in the aquatic environment

16.2 Fully text to the H-Sentences mentioned:
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H315 - Causes skin irritation
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 - Causes serious eye irritation
H302 Harmful if swallowed.
H331 Toxic if inhaled.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.
H350 May cause cancer.
H400 Very toxic to aquatic life.
H402 - Harmful to aquatic life
H412 Harmful to aquatic life with long lasting effects

16.3 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.