



KIT CLART[®] CMA EGFR

NOTE:

GENOMICA provides safety data sheet only for the hazardous components of the KIT CLART[®] CMA EGFR

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.3: 01.09.2015

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

1.1. Product identifiers

Product name: CLART® CMA EGFR

1.2 Relevant identified uses of the mixture and uses advised against

DETECTION AND GENETIC IDENTIFICATION OF POINT MUTATIONS, INSERTIONS AND DELETIONS IN THE GENE EGFR PATHWAY ASSOCIATED TO NON SMALL CELL LUNG CANCER FOR IN VITRO DIAGNOSIS

CLART® CMA EGFR detects the presence of the most prevalent mutations in the Epidermal Growth Factor Receptor (EGFR) gene associated to non-small-cell lung cancer.

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)

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2. Classification and Hazards identification

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.

GENOMICA states that the product CLART[®]CMA EGFR is in compliance with directive 98/79/CE therefore shall not apply the regulation (EC) No 1272/2008. Regarding to labelling of CLART[®]CMA EGFR follows Directive 98/79/EC, UNE-EN 980, ISO 18113 and ISO 15223.

Classification according to the [Regulation 67/548/EC](#) , [directive 1999/45/EC](#) and [Regulations 1907/2006/EC](#)

According to the product CLART[®]CMA EGFR does not require a Material Safety Data Sheet as it contains a quantity not exceeding 1% of components classified as dangerous as and not greater than 0.1% of components classified as carcinogenic.

2.2 . Hazards identification

- **Skin corrosion/irritation**
- **Serious eye damage/eye irritation**
- **Acute Toxicity**
- **Carcinogens**
- **Harmful to aquatic life**
- **Respiratory Irritation**
- **Skin / respiratory Sensibilization**
- **Specific target organ toxicity - single exposure**

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.



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3. Composition/ information on ingredients




Dangerous components According to EU Directives 67/548/EEC or 1999/45/EC 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.**

SH (Hybridisation solution)	Classification	Pictogram, Signal Word Code(s)	Hazard statement Code(s)
SDS 10% SOLUTION Sodium lauryl sulfate CAS-No. : 151-21-3 EC-No. : 205-788-1	According to EU Directives 67/548/EEC or 1999/45/EC this substance is classified as : - Xn: Harmful, According to Regulation No 1272/2008. this substance is classified as: - Skin corrosion/irritation (Category 2) - Serious eye damage/eye irritation (Category 2B)	Warning! 	R36/37/38 H315,H319,H402
RE (Developer):	Classification	Pictogram, Signal Word Code(s)	Hazard statement Code(s)
3,3'-dimethoxybenzidine o-dianisidine CAS-No. : 119-90-4 EC-No. : 204-355-4 ,	According to EU Directives 67/548/EEC or 1999/45/EC this substance is classified as : - Xn: Harmful According to Regulation No 1272/2008. this substance is classified as: - Acute Toxicity (category 4) - Carcinogens(category 1B)	Danger! 	R22, R45, H302, H350

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<p>Citric acid monohydrate CAS-No. : 5949-29-1 EC-No. : 201-069-1</p>	<p>According to EU Directives 67/548/EEC or 1999/45/EC this substance is classified as :</p> <ul style="list-style-type: none"> - Xi: Irritant <p>According to Regulation No 1272/2008. this substance is classified as:</p> <ul style="list-style-type: none"> - Eye Irritant (Category 2) 	<p>Warning!</p> 	<p>R36 H319</p>
<p>5-Chloro-2-methyl-4-isothiazolin- 3-one CAS-No.: 26172-55-4 EC-No. : 247-500-7</p>	<p>According to 67/548/EWG , 1999/45/EG This substance is classified as :</p> <ul style="list-style-type: none"> - Xn: Harmful - C: Corrosive <p>According to Regulation No 1272/2008. This substance is classified as:</p> <ul style="list-style-type: none"> - Skin corrosion (Category 1B) - Respiratory sensitisation (Category 1) - Skin sensitisation (Category 1) 	<p>Danger!</p> 	<p>R42/R43, R34, H314,H317,H334</p>
<p>2-Methyl-2H-isothiazol-3-one Reach register :Not available CAS-No. : 2682-20-4 EC-No. : 220-239-6</p>	<p>According to EU Directives 67/548/EEC or 1999/45/EC ,this substance is classified as :</p> <ul style="list-style-type: none"> - Xi: Irritant - T :Toxic - N: Dangerous for the environment 	<p>Danger!</p> 	<p>R22, R23, R34, R43, R50</p>

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	<p>According to Regulation (EC) No 1272/2008, this substance is classified as :</p> <ul style="list-style-type: none"> - 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) 		<p>H302,H331,H314,H317,H335 ,H400</p>
<p>hydrogen peroxide CAS-No. : 7722-84-1 EC-No. : 231-765-0</p>	<p>According to EU Directives 67/548/EEC or 1999/45/EC this substance is classified as :</p> <ul style="list-style-type: none"> - Xn: Harmful - Xi: Irritant <p>According to Regulation No 1272/2008 . this substance is classified as:</p> <ul style="list-style-type: none"> - Acute toxicity, Oral (Category 4) - Serious eye damage (Category 1) 	<p>Danger!</p> 	<p>R22,R41, H302,H318,</p>

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. 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

The product itself is not inflammable; extinguishing measures should therefore be prepared for an environmental fire. 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

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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

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

Chemical Name	EU OEL (TWA)	EU OEL (STEL)	EU Skin Notation
Sodium lauryl sulfate 151-21-3	None	None	None

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.

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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 developer

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

Acute toxicity of the hybridisation solution

Chemical Name	LD50 (oral, rat/mouse)	LD50 (dermal, rat/rabbit)	LC50 (inhalation, rat/mouse)
Sodium lauryl sulfate	= 1288 mg/kg (Rat)	No data available	>3900mg/m ³ (Rat)

11.2 Skin Corrosion/Irritation

No information available

11.3 Serious Eye Damage/Irritation

No information available

11.4 Respiratory Or Skin Sensitization

No information available

11.5 Germ Cell Mutagenicity

No information available

11.6 Carcinogenicity

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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

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 (see chapter 15.1).

Acute aquatic toxicity of the hybridisation solution

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

Chemical Name	Freshwater Algae Data	Water Flea Data	Freshwater Fish Species Data	Microtox Data	log Pow
Sodium lauryl sulfate 151-21-3	Desmodesmus subspicatus EC5030 - 100 mg/L (96 h) Pseudokirchneriella subcapitata EC503.59 - 15.6 mg/L (96 h) Pseudokirchneriella subcapitata EC50=117 mg/L (96 h) Desmodesmus subspicatus EC50=53 mg/L (72 h)	Daphnia magna EC50=1.8 mg/L (48 h)			logPow1.6

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.

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12.6 Other Adverse Effects

No further effects known.

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 1907/2006](#) of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

16. Other information

The information contained herein is considered accurate and is based on our current knowledge, accordingly, it should only be given an orientative use.

16.1 Fully text to the R-Phrases mentioned

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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.
R45 May cause cancer
R50 Very toxic to aquatic organisms.

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

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.