

Created on: 30.01.2020
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Version: 01

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

1.1 Product identifier

Substance Name / Trade Name: 5-Gene-Multiplex 1% AF cfDNA in Plasma,
BRAF/KRAS/PIK3CA/AKT1/ERBB2

Index No.: not available

EC-No.: not available

CAS-No.: not available

REACH No.: There is no registration No. for this mix.

Other names: not available

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

Relevant identified uses:

Use as laboratory reagent – for scientific research and development

Uses advised against:

Not for consumer use.

1.3 Details of the supplier of the safety data sheet

Manufacturer / Supplier: SensID GmbH

Street/PO Box: Schillingallee 68

Country-Code/Postcode/City: D-18057 Rostock

Point of contact for technical Support

Phone / Fax / E-Mail

+49(0)38137718201 / +49(0)38137718200 / E-Mail: support@sens-id.com

1.4 Emergency Phone No.

SensID GmbH +49 (0) 38137718201 (Reachability: on weekdays 8-16 o'clock)

Section 2: Hazards identification

2.1 Classification

Classification according to Regulation (EC) No 1272/2008:

mixture contains < 1% EDTA; CAS No. 60-00-4

Corrosive/irritant effect on the skin – Category 2

Severe eye damage / irritation – Category 2A

2.2 Label elements

Label elements according to (EC) No. 1272/2008

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Pictogram:

GHS07

Signal word: Attention

Hazard-determining components for labelling contains:

Hazard statements:

H315 – Causes skin irritation

H319 – Causes serious eye irritation

Precautionary statements:

P332+P313 – If skin irritation occurs: Get medical advice/attention

P362 – Remove contaminated clothing and wash before wearing again

P264 – Wash exposed skin thoroughly after handling

P280 – Wear eye protection, face protection, protective clothing, protective gloves

P305+P351+P338 – If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337 +P313 – If eye irritation persists: Get medical advice/attention

Other labelling elements

EU notes on specific hazards:

R-phrases

R36/38 – Irritating to eyes and skin

S-phrases

S26 – After contact with eyes, rinse immediately with plenty of water and seek medical advice

S24/25 – Avoid contact with eyes and skin

S36/37/39 – Wear suitable protective clothing, gloves and eye/face protection

2.3 Other Hazards

Physical hazards

Harmless

Specific effects

No carcinogenic effects

No genetic alteration

No reproductive toxicity

No sensitization

Section 3: Composition/Information on Ingredients

3.1 Substances

Any concentration specified as a range is used to protect confidentiality.

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Main component of the substance

Substance name: Human plasma (technically modified)

Index no.: not available

EC no.: not available

Impurities, stabilising additives and individual components

Substance name: sodium chloride 0,1 – 1%

Index no.: not available

EC no.: not available

CAS No: 7647-14-5

3.2 Mixtures

here are no additional ingredients which, according to the supplier's current state of knowledge and in the applicable concentration, are classified as hazardous to health or the environment and subject to notification.

Section 4: First aid measures

4.1 Description of first aid measures

After inhalation

Take him out into the fresh air. In case of respiratory arrest with additional oxygen artificial respiration. Immediately call a poison control center or doctor.

After skin contact

Immediately rinse with plenty of water for at least 15 minutes. Remove contaminated clothing and wash before wearing again. Immediate medical attention is required.

After eye contact

Immediately rinse thoroughly with plenty of water for at least 15 minutes, also under the eyelids. Immediate medical attention is required.

After ingestion

Immediately call a poison control centre or doctor. Never give water to an unconscious person. Do not induce vomiting without doctor's orders.

4.2 Most important symptoms and effects, both acute and delayed

The main known symptoms and effects are described on the label (see section 2.2) and/or in Chapter 11.

4.3 Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

Section 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: water spray, Carbon dioxide (CO₂), foam, dry chemicals

Unsuitable extinguishing media: not available

5.2 Special hazards arising from the substance or mixture

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Hazardous combustion products: No further known.

5.3 Advice for fire fighter

Wear self-contained breathing apparatus and protective clothing.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions

Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

Personal protective equipment

Use personal protective equipment.

6.2 Environmental precautions

Avoid further leakage or spillage if safe to do so. Do not discharge into drains or rivers.

6.3 Methods and material for containment and cleaning up

For containment

Prevent further leakage or spillage if safe to do so.

For cleaning up

Soak up with inert absorbent material

6.4 Reference to other sections

See section 12 for additional information.

Section 7: Handling and Storage

7.1 Precautions for safe handling

Avoid contact with skin, eyes and clothes. Wear personal protective equipment.

7.2 Conditions for safe storage, including any incompatibilities

Information on storage conditions

Store in a dry, cool and well-ventilated place. Store in properly labelled containers, avoid direct sunlight. Keep container tightly closed until ready for immediate use. Opened containers must be carefully closed and stored upright. Do not store in unmarked containers.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values and/or biological limit values Occupational exposure limit values (OELs) Germany

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Contains no substances with occupational exposure limits according to Regulation (EC) No 1272/2008.

8.2 Exposure controls / Personal protective equipment

Suitable technical control equipment

Provide adequate ventilation, especially in confined areas.

Personal protective equipment

Eye / face protection: Safety glasses with side protection.

Skin protection: Impermeable gloves.

Other skin protection: Light protective suit

Respiratory protection

With aerosol or mist formation. Filter device (EN141) type E against acidic gases.

Heat / Cold protection

No action needed.

Environmental exposure controls

No data available.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	liquid
Appearance:	light yellow
Odour:	no information available
Odour threshold:	no information available
pH-value:	no information available
Melting point/Freezing point:	Mixture has not been tested
Boiling point / boiling range:	Mixture has not been tested
Flash point:	Mixture has not been tested
Evaporation rate:	Mixture has not been tested
Flammability (solid, gas):	Mixture has not been tested
Upper/Lower flammability or explosive limits:	Mixture has not been tested
Vapor pressure:	no information available
Vapor density:	no information available
Relative Density:	no information available
Solubility:	no information available
Partition: n-octanol/water:	no information available
Decomposition temperature:	no information available
Auto-ignition temperature:	no information available
Viscosity:	no information available
Explosive properties:	Mixture has not been tested
Oxidising properties:	Mixture has not been tested

9.2 Other informationSonstige Angaben

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No data available

Section 10: Stability und Reactivity

10.1 Reactivity:

Not known under normal environmental conditions.

10.2 Chemical stability:

Stable under normal conditions and under the temperature and pressure conditions expected during storage and handling.

10.3 Possibility of hazardous reactions:

No information available.

10.4 Conditions to avoid:

Do not mix with ammonium oxides (NO_x).

10.5 Incompatible materials:

No information available.

10.6 Hazardous decomposition products:

None in normal processing.

Abschnitt 11: Toxicological information

11.1 Information on toxicological effects

Chemical name	LD50 (oral, rat)	LD 50 (dermal, rabbit)
Sodium chloride 7647-14-5	3000 mg/kg	>10.000 mg/kg
Chemical name	LD50 (oral, Ratte)	
Editic acid (EDTA) 60-00-4	2580 mg/kg	

	Sodium chloride 7647-14-5	Editic acid (EDTA) 60-00-4
Acute toxicity:	Is not acutely toxic.	Based on the available data, the classification criteria are not met.
Skin corrosion / irritation:	Is not classified as corrosive / irritant.	Leichte Reizung
Eye damage / irritation:	Is not classified as seriously damaging to the eyes or irritating to the eyes.	Verursacht schwere Augenreizung
Sensitisation to the respiratory tract/skin:	Is not classified as an inhalation or skin allergen	Based on the available data, the classification criteria are not met.
Germ cell mutagenicity:	Not classified as germ cell mutagen.	Based on the available data, the classification criteria are not met.
Carcinogenicity:	Not classified as a carcinogen.	Based on the available data, the classification criteria are not met.
Reproductive toxicity:	Not classified as toxic to	Based on the available data, the

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	reproduction.	classification criteria are not met.
STOT – single exposure:	Is not classified as specific target organ toxicant (single exposure).	Based on the available data, the classification criteria are not met.
STOT – repeated exposure:	Is not classified as specific target organ toxicant (repeated exposure).	Based on the available data, the classification criteria are not met.
Aspiration hazard:	Is not classified as aspiration hazard.	Based on the available data, the classification criteria are not met.
Symptoms related to the physical, chemical and toxicological characteristics	In case of ingestion: Vomiting, nausea. In case of eye contact: causes mild to moderate irritation In case of inhalation: No data available In case of skin contact: essentially non-irritant Further information: None Information on toxicokinetic, metabolism and distribution: No information available.	In case of ingestion: No data available In case of eye contact: causes severe irritation In case of inhalation: No data available In case of skin contact: slight irritant effect Further information: None Information on toxicokinetic, metabolism and distribution: No information available.

Section 12: Ecological information

	Natriumchlorid 7647-14-5	EDTA (Editinsäure) 60-00-4
12.1 Ecotoxicity:	according to 1272/2008/EC: Not to be classified as hazardous to water	EC50 bacteria (16 hours) 28 mg/l MSDS LC50 fish (96 hours) Minimum value: 41 mg/l Maximum value: 532 mg/l (GESTIS-substance database) EC50 crustaceans (48 hours) Minimum value: 113 mg/l Maximum value: 113 mg/l (GESTIS-substance database)
12.2 Persistence and degradability:	The methods for determining biodegradability are inorganic substances not applicable.	Not easily biodegradable.
12.3 Bioaccumulative potential:	No data available	
12.4 Mobility in soil:	No data available	
12.5 Results of PBT- and vPvB-assessment:	No data available	
12.6 Other adverse effects:	Weak Water endangering (AwSV)	WGK 2: hazardous to water Do not allow to enter ground water, water bodies or sewage system.

Section 13: Disposal considerations

13.1 Waste treatment methods

Must not be disposed of together with household waste. Do not discharge into drains.
 Hand over hazardous waste collector or take to hazardous waste collection point.

Treatment of contaminated packaging

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Disposal according to official regulations.

Waste code according to Waste Catalogue Ordinance (AVV)
18 02 05*

Special precautions

Collection of small quantities: Do not put waste in sinks or bins. Place in collection container for liquid organic residues. Collection containers must be clearly labelled with the systematic designation of their contents. Keep containers in a well-ventilated place. Hand them over to the competent authority for disposal.

relevant EU or other provisions

Not required.

Section 14: Transport information

Transport information is omitted as no special conditions apply.

Section 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) No 648/2004 (Detergents Regulation): listed
There is no further listing in the relevant European Union (EU) regulations.

National regulations Germany:

Water hazard class

WGK 2 (List classification): hazardous to water

TRGS: ASR A1.3 Observe eye protection

TRGS 201, TRGS 400, TRGS 600, TRGS 500, TRGS 509, TRGS 510, TRGS 800

Other relevant regulations

The substance is classified and labelled according to the CLP Regulation: GHS07

Signal word: Attention

REACH Art. 57: is not included

15.2 Chemical safety assessment

DGUV Regel 112-195

Use of protective gloves Updated reprint October 2007

Section 16: Other information

The information in this SDS is provided in good faith based on our knowledge, but they do not constitute an assurance of product properties and do not establish a contractual relationship. The information contained in this SDS should not be considered as exhaustive and only serve as a guide. All materials and mixtures can harbour unknown hazard and should be used with care. Since conditions of use of the product are not under the control of SensID GmbH, it is the duty of the buyer/user to determine the necessary conditions for the safe use of the product. SensID GmbH will not be liable for any damages resulting from handling or contact with the product.

Changes compared to the last version:

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No change, version 01.
Section 3 Composition changed, version 02.

Important literature and data sources:

- Regulation (EC) No 1907/2006 (REACH), as amended by 2015/830 / EU
- Regulation (EC) No 1272/2008 (CLP, EU-GHS)

Abkürzungen

CAS	Chemical Abstracts Service ((database of chemical compounds and their unique key, the CAS Registry Number)
CLP	Classification, Labelling and Packaging of substances and mixtures
DGUV	German statutory accident insurance
EC50	mean effective concentration
EDTA	Editic acid
EC	European Community
EC-Nr.	EC-No. The EC Inventory (EINECS, ELINCS and the NLP directory) is the source of the seven-digit EC number as a substance index in the European Union
Index-Nr.	The index number is the identification code specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal concentration
LD50	Lethal dose
MARPOL	International Convention for the Prevention of Pollution from Ships (abbreviation of "Marine Pollutant")
mg/kg	Milligrams per kilogram
mg/l	Milligrams per litre
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Regulation (EC) No 1907/2006 (REACH Regulation)
TRGS	Registration, Evaluation, Authorization and Restriction of Chemicals
vPvB	Technical rules for hazardous substances
	very Persistent and very Bioaccumulative (sehr persistent und sehr bioakkumulierbar)
WGK	Water quality class
STOT	specific target organ toxicant

End of safety data sheet.