

SAFETY DATA SHEET according to Regulation (EC) Nr. 1907/2006

Created on: 30/09/2022  
Valid from: 30/09/2022  
Revised on: 30/09/2022  
Version: 02  
Replaced Version: 01



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

**1.1 Produktidentifikator**

Product identifier SID-000114

Substance name /Trade name: Idylla™ MSI FFPE Reference Set

Index No.: not available

EC-No.: not available

CAS-No.: not available

REACH No.: not available

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

**Relevant identified uses:**

Reference material for In vitro Diagnostic (IVD) use

Contents of the set:

SID-000116 Idylla™ MSI 0 % FFPE Reference Standard

SID-000117 Idylla™ MSI 16.67 % FFPE Reference Standard

**Uses advised against:**

Not for consumer use.

**1.3 Details of the supplier of the safety data sheet**

Manufacturer /Supplier: SensID GmbH

Street/Street number: Schillingallee 68

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

Point of contact for technical support

Telephone +49(0)381 377 182 01

Fax +49(0)381 377 182 00

E-Mail info@sens-id.com

**1.4 Emergency phone number**

SensID GmbH +49(0)381 377 182 01

(Availability: on weekdays 8-16 o'clock; CET)

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## Section 2: Hazard identification

### 2.1 Classification

Classification according to Regulation (EC) No 1272/2008

The package contains FFPE curls with human cells. No dangerous substance or dangerous mixture.

No hazardous ingredient is present in an amount that requires labeling.

### 2.2 Label elements

Not required

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

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Hazard-determining components for labelling contains:

Hazard statements: not required

Precautionary statements: not required

Other labelling elements

EU notes on specific hazards: not required

### 2.3 Other dangers

#### Physical hazards

harmless

#### Specific effects

No carcinogenic effects

No genetic alteration

No reproductive toxicity

No sensitization

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## Section 3: Composition/Information on ingredients

### 3.1 Substances

Not applicable, mixture

### 3.2 Mixtures

There are no ingredients that are reportable or classified as hazardous to health or environment according to the current state of knowledge of the supplier in the applicable concentration.

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## Section 4: First aid measures

### 4.1 Description of the first aid measures

#### Following inhalation

Move to fresh air. In case of respiratory arrest give artificial respiration with additional oxygen.

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| <b>Following skin contact</b> | The product does not irritate skin. Wash off with plenty of water. remove contaminated clothing as a precaution.     |
| <b>Following eye contact</b>  | Rinse out with plenty of water with the eyelids held wide open. Arrange medical treatment.                           |
| <b>Following ingestion</b>    | Wash mouth out with water. Never give water to an unconscious person. Do not induce vomiting without medical advice. |
- 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**  
No data available.
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## Section 5: Firefighting measures

- 5.1 Extinguishing media**  
**Suitable:** Extinguishing media: water spray, Carbon dioxide (CO<sub>2</sub>), foam, dry chemicals  
**Unsuitable:** Extinguishing media: not available
- 5.2 Special hazards arising from the substance or mixture**  
Hazardous combustion products: No further known.
- 5.3 Advice for fire fighters**  
Wear self-contained breathing apparatus and protective clothing.
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## 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 8 for Personal protective equipment  
See section 13 for disposal
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## Section 7: Handling and storage

### 7.1 Precautions for safe handling

Avoid contact with skin, eyes and clothes. Wear personal protective equipment (see section 8)

### 7.2 Conditions for safe storage, including any incompatibilities Information on storage conditions

General good laboratory practice should be maintained. Store in properly labelled containers. Keep container tightly closed until ready for immediate use. Do not store in unmarked containers. Take care to keep workplace clean and dry. Avoid general contact by handling, wear gloves and lab coat. Store the package with the lids tightly closed at 2-8°C preferably in the dark.

#### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

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## Section 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational exposure limits / or biological values

No known values.

### 8.2 Exposure controls/personal protection Exposure controls

Provide adequate ventilation, especially in confined areas.

#### Personal protective equipment

##### Eye / face protection:

Wear suitable safety goggles if required by valid guidelines or your own risk assessments in the laboratory.

##### Skin / body protection:

Wear suitable protective clothing and gloves if required by valid guidelines or your own hazard assessments in the laboratory.

##### Other body protection:

No action needed.

##### Respiratory protection:

No action needed.

##### Heat / Cold protection:

No action needed

#### Environmental exposure controls

See Section 12.

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## Section 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state:	Solid
Appearance:	White color, translucent
Odour:	Odorless
Odour threshold:	No information available
pH-value:	No information available
Melting point/Freezing point:	56 °C / 132.8 °F Melting
Boiling point / boiling range:	> 288 °C / 550.4 °F
Flash point:	> 204 °C / > 399.2 °F
Evaporation rate:	No information available
Flammability (solid, gas):	No information available
Upper/Lower flammability or explosive limits:	No information available
Vapor pressure:	< 0.1 mmHg @ 20 °C
Vapor density:	0.81 g/l
Relative Density:	No information available
Solubility:	No information available
Partition: n-octanol/water:	No data 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 information  
 No data available.

## Section 10: Stability and Reactivity

10.1 Reactivity:  
 Not known under normal environmental conditions.

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- 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:**  
The product should not be exposed to temperatures above 55°C to prevent melting of the paraffin.
- 10.5 **Incompatible materials:**  
No information available.
- 10.6 **Hazardous decomposition products:**  
None in normal processing.
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## Section 11: Toxicological information

### 11.1 Information on toxicological effects

- Acute Toxicity:** No information available.
- Skin corrosion / irritation:** No information available.
- Eye damage / irritation:** Is not classified as seriously damaging to the eyes or irritating to the eyes.
- Sensitisation to the respiratory tract/skin:** Is not classified as an inhalation or skin allergen.
- Germ cell mutagenicity:** Not classified as germ cell mutagen.
- Carcinogenicity:** Not classified as a carcinogen.
- Reproductive toxicity:** Not classified as toxic to reproduction.
- STOT – single exposure:** Is not classified as specific target organ toxicant (single exposure).
- STOT – repeated exposure:** Is not classified as specific target organ toxicant (repeated exposure).
- Aspiration hazard:** Is not classified as aspiration hazard.

### 11.2 Symptoms related to the physical, chemical and toxicological characteristics

- In case of ingestion:** No information available.
- In case of eye contact:** No information available.
- In case of inhalation:** No information available.
- In case of skin contact:** No information available.
- Further information:** No information available.

- ### 11.3 Information on toxicokinetic, metabolism and distribution:
- No information available.
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## Section 12: Ecological information

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| 12.1 Ecotoxicity                          | No information available.<br>The fabric is easily biodegradable. |
| 12.2 Persistence and degradability:       | No information available   |
| 12.3 Bioaccumulative potential:           | No information available   |
| 12.4 Mobility in soil:                    | No information available.  |
| 12.5 Results of PBT- and vPvB-assessment: | No information available.  |
| 12.6 Other adverse effects:               | No information available.<br>The fabric is easily biodegradable. |

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## Section 13: Disposal considerations

- 13.1 **Waste treatment methods**  
No special procedures known. If necessary, clarify with the local disposal companies whether the product used is classified as dangerous.
- 13.2 **Treatment of contaminated packaging**  
Disposal according to official local regulations.
- 13.3 **Waste code according to Waste Catalogue Ordinance**  
Waste code according to official local regulations.
- 13.4 **Special precautions**  
No special actions required.
- 13.5 **relevant EU or other provisions**  
Not required.

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## Section 14: Transport information

Transport information is omitted as no special conditions apply.

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## Section 15: Regulatory information

- 15.1 **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
There is no listing in the relevant provisions of the European Union (EU). All medical devices imported into the United States (U.S.) must meet the regulatory requirements of both the U.S. Bureau of Customs and Border Protection (CBP) and FDA.  
Relevant regulations:  
Infectious Substances Shipping Guidelines (ISSG)  
IATA Dangerous Goods Regulations  
ADR amendment regulation
- 15.2 **Chemical safety assessment**  
Not available.

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## 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.

### 16.1 Changes compared to the last version:

Version 02: Formatting the page breaks in the template

### 16.2 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)

### 16.3 Abbreviation

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
EG	European Community
EG-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
PBT	Persistent, Bioaccumulative and Toxic
REACH	Regulation (EC) No 1907/2006 (REACH Regulation) Registration, Evaluation, Authorization and Restriction of Chemicals
vPvB	very Persistent and very Bioaccumulative

End of safety data sheet.