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Safety Data Sheet

In accordance with Commission regulation EU n° 453/2010 No. 1907/2006 and Commission regulation EU n°830/2015

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

1.1 Product identifier

Product code:

RST1

Product name:

ResiScreen® Staph.

Chemical name:

N/A

REACH registration number:

No registration number is given yet for this substance since the annual import quantity is less than one tonnage per annum.

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

Relevant identified uses:

For *in vitro* diagnostic use only. Reagent for *in vitro* diagnostic kit.

Uses advised against:

Not for consumer use.

1.3 Details of the supplier of the safety data sheet

Molsid SAS

60 F Avenue Rockefeller

Bâtiment Bioserra 2

69008 Lyon, France

contact@molsid.com


1.4 Emergency telephone numbers

France ORFILA +33 (0)1 45 42 59 59

Section 2: Hazards identification

2.1 **Classification of the substance or mixture**

According to Regulation (EC) n° 1272/2008.

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GHS Hazard Classification

Is not a hazardous substance or mixture in accordance with the regulation.

GHS Hazard Statement

Is not a hazardous substance or mixture in accordance with the regulation.

GHS Precautionary Statements

Is not a hazardous substance or mixture in accordance with the regulation.

2.2 Label element:

N/A

2.3 Other hazards:

N/A

Section 3: Composition/information on ingredients

3.1 Substances

N/A

3.2 Mixtures

Name	Product identifier	Weight percentage	Classification According to Regulation (EC) n° 1272/2008.
352600-C	N/A	0.1%	Skin sensitization H317
Dimethylsulfoxyde	CAS 67-68-5	99.9%	Not a hazardous substance

Section 4: First aid measures

4.1. Description of first aid measures

General advice: If medical attention is required, show this safety data sheet to the doctor.

If Inhaled: move person to fresh air and call a GP if feeling unwell.

In Case of Skin contact: Wash affected area with soap and water. Consult a physician if any exposure symptoms are observed.

In Case of Eye Contact: Immediately rinse eyes with plenty of water for at least 15 minutes. Consult a physician.


If Swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Do NOT induce vomiting unless advised to do so by a physician or Poison Control Center. Seek medical attention.

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

H317 May cause an allergic skin reaction.

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

Treat symptomatically

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If skin irritation occurs, get medical attention.

Section 5: Firefighting measures

5.1. Extinguishing media

Suitable: Water spray, carbon dioxide, foam.

5.2. Special hazards arising from the substance or mixture

No data available

5.3. Advise for fire-fighters

Do not act without suitable protective equipment. Self-contained breathing apparatus and protective suit.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Use personal protective equipment.

Suitable: Water spray, carbon

6.1.2. For emergency responders

Use suitable protective equipment.

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3. Methods and material for containment and cleaning up

Take up mechanically and place in appropriate containers following local regulations.

6.4. Reference to other sections


See section 8.

Section 7: Handling and storage

7.1. Precaution for safe handling

Wear personal protective equipment. Do not get in eyes, on skin or on clothing. Do not ingest. Ensure good ventilation.

7.2. Conditions for safe storage, including any incompatibilities

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Keep in properly labelled containers in a dry atmosphere. Store in accordance with local regulations. Store in a fridge (2-6°C).

7.3. Specific end use(s)

For *in vitro* diagnostic use. Reagent for *in vitro* diagnostic kit. Not for use in human or animals.

Section 8: Exposure controls/personal protection

8.1. Control parameters

N/A

8.2. Exposure controls

Personal protective equipment: All recommendations below are advisory in nature and a risk assessment should be performed by the employer/end user prior to use of this product. The type of protective equipment must be selected based on the amount and concentration of the dangerous material being used in the workplace.

Eye protection: Safety goggles or face shield. All equipment should have been tested and approved under appropriate standards, such as NIOSH (US) or EN 166 (EU).

Hand protection: Gloves should be used when handling this material. Gloves are to be inspected prior to use. Contaminated gloves are to be removed using proper glove removal technique so that the outer surface of the glove does not contact bare skin. Dispose of contaminated gloves after use in compliance with good laboratory practices and local requirements. Gloves used for incidental exposures (splash protection) should be designated as “chemical resistant” by EU standard EN 374 with the resistance codes corresponding to the anticipated use of the material. Unrated gloves are not recommended.

Respiratory protection: ensure proper ventilation

8.3. Environmental exposure controls

Do not let product enter drains.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Slight yellow pale or incolor solution

Odour: No data available


Odour threshold: No data available

pH: No data available Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: No data available

Evaporation rate: No data available

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Flammability (solid, gas): No data available Upper/lower flammability or explosive limits: No data available

Vapour pressure: No data available

Vapour density: No data available

Relative density: No data available

Solubility(ies): Can be diluted in most solvents.

Partition coefficient: n-octanol/water: No data available

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity: No data available

Explosive properties: No data available

Oxidizing properties: No data available

9.2 Other information

No additional information available.

Section 10: Stability and reactivity

10.1. Reactivity

Non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Not reported under normal conditions of use.

10.4. Conditions to avoid

None under normal conditions of storage and use.

10.5. Incompatible materials


None.

10.6. Hazardous decomposition products

Under normal conditions of use and storage, decomposition products should not be produced.

Section 11: Toxicological information

11.1. Information on toxicological effects

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Acute toxicity: not classified.

Skin corrosion/irritation: not classified.

Serious eye damage/irritation: not classified.

Respiratory or skin sensitization: May cause skin sensitization.

Germ cell mutagenicity: not classified.

Carcinogenicity: not classified.

reproductive toxicity: not classified.

STOT-single exposure: not classified.

STOT-repeated exposure: not classified.

Aspiration hazard: not classified.

Section 12: Ecological information

12.1. Toxicity

No data available.

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.

No data available.


12.6. Other adverse effects

No data available.

Section 13: Disposal considerations

13.1. Waste treatment methods

Use containers following local regulations about chemical waste treatment.

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Section 14: Transport information

14.1. UN number

N/A.

14.2. UN proper shipping name

N/A.

14.3. Transport hazard class(es)

N/A.

14.4. Packing group

N/A.

14.5. Environmental hazards

N/A.

14.6. Special precautions for user

N/A.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code.

N/A.

Section 15: Regulatory information

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

No REACH restrictions.

Not subject to restricted substances under EC 1907/2006, Annex XVII


Not listed under Annex I of Regulation (EC) n° 689/2008

Not subject to restricted substances under Annex V of Regulation (EC) 689/2008

Not subject to Regulation (EC) n° 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC

15.2. Chemical safety assessment

A toxicological assessment of 352600-C was performed, which was based on Quantitative Structure-Activity Relationship (Q)SAR approach according to ICH M7 guideline (ICH M7, 2017). The ICH M7 class was 5: no structural alerts, or alerting structure with sufficient data to demonstrate lack of mutagenicity or carcinogenicity.

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Section 16: Other information

The information contained in this safety data sheet is accurate to the best of our knowledge and understanding at the date of publication. This information is provided for guidance only to ensure the safe handling, use, processing, storage, transport, disposal, and marketing of the substance, and should not be considered as a guarantee or quality assurance.

The information applies solely to the specifically described material and may not be valid if the material is used in combination with any other substance or in any other process, unless otherwise stated in the text.