

Safety Data Sheet

section

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

1.1 Product identifier

Trade name/designation : Clarity RSV Antigen Test - Extraction Reagent.

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

Relevant identified uses : The Clarity RSV Antigen Test - Extraction Reagent is a component used in the test that is intended for the rapid, qualitative detection of respiratory syncytial virus fusion protein directly from nasopharyngeal swab, and nasal aspirate specimens in children less than 6 years and adults over the age of 60. The test is intended for use as an aid in the rapid laboratory diagnosis of acute respiratory syncytial virus infection in patients with symptoms consistent with RSV infection.

Uses advised against : No data available.

1.3 Details of the supplier of the safety data sheet

Supplier : **Name:** Clarity Diagnostics, LLC
Street: 1080 Holland Drive, Suite 1
City/State/Postal Code: Boca Raton, FL, 33487
Country: United States
Telephone: (877) 485-7877
Website: www.ClarityDiagnostics.com

1.4 **Emergency Telephone Number** Telephone: 877.485.7877

section

2 Hazards identification

2.1 Classification of the substance or mixture

Hazards identification: This mixture is not classified as dangerous.

2.2 Label elements

Labelling

Hazard pictograms Not Applicable

Signal word Not Applicable

section

3 Composition/information on ingredients

3.2 Mixtures

In accordance with the product knowledge, no nanomaterials have been identified.
This product does not contain any hazardous ingredients at or above regulated thresholds.

Remark

Full text of H- phrases: see section 16.

section

4 First aid measures

4.1 Description of first aid measures

General information:

When in doubt or if symptoms are observed, get medical advice.

Following inhalation:

No special measures are necessary.

Provide fresh air.

Following skin contact:

Wash with soap and water.

Following eye contact:

In case of eye irritation consult an ophthalmologist.

Rinse immediately carefully and thoroughly with eye-bath or water.

Following ingestion:

IF SWALLOWED: Rinse mouth.

Do NOT induce vomiting.

Self-protection of the first aider:

No special measures are necessary.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor:

Treat symptomatically.

section

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Foam.

Extinguishing powder.

Carbon dioxide (CO₂).

Sand.

Unsuitable extinguishing media:

Strong water jet.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3 Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information

Do not inhale vapors and fumes.

Co-ordinate fire-fighting measures to the fire surroundings.

Move undamaged containers from immediate hazard area if it can be done safely.

Use caution when applying carbon dioxide in confined spaces. carbon dioxide can displace oxygen. Use water spray jet to protect personnel and to cool endangered containers.

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

section **6** Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protection equipment.

6.2 Environmental precautions

Ensure that waste is collected and contained.

Contain leaks or spills within cabinets with removable trays.

6.3 Methods and material for containment and cleaning up

Treat the recovered material as prescribed in the section on waste disposal.

Collect in closed and suitable containers for disposal.

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

Wipe up with absorbent material (eg. cloth, fleece).

6.4 Reference to other sections

Safe handling: see section 7.

Disposal: see section 13.

Personal protection equipment: see section 8.

Additional information

Not available

section **7** Handling and Storage

7.1 Precautions for safe handling

PROTECTIVE MEASURES:

No special measures are necessary.

Advices on general occupational hygiene:

Wash hands before breaks and after work.

Remove contaminated, saturated clothing.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry, cool, and well-ventilated place. Store at 2–30C. Keep container in upright position in order to prevent leakage.

Advice on joint storage:

Keep away from food, drink and animal feeding stuffs.

7.3 Specific end uses

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8 Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits:

Does not contain substances above concentration limits fixing an occupational exposure limit.

Biological limit values:

Not available

Exposure limits at intended use:

Not available

Remark:

Not available

8.2 Exposure controls

Appropriate engineering controls:

See section 7. No additional measures necessary.

Individual protection measures, such as personal protective equipment: Not available

Eye/face protection : **Suitable eye protection:**
Wear eye protection equipment.

Skin protection : **Hand protection:**
Suitable gloves type:
Wear protective gloves.
Body protection:
Suitable protective clothing:
No special measures are necessary. Lab coat.

Respiratory protection : **Suitable respiratory protection apparatus:**
No data available.

Environmental exposure controls:

No special measures are necessary.

Consumer exposure controls:

Not available

Additional information

Not available

9 Physical and chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	:	Liquid
Color	:	Clear
Odor	:	None
Odor threshold	:	Not determined
pH	:	8.0
Melting/Freezing point	:	Not determined
Boiling point	:	Not determined
Flash point	:	Not determined
Evaporation rate	:	Not determined
Flammability	:	Not determined
Lower limit of flammability or explosive	:	Not determined
Vapor pressure	:	Not determined
Vapor density	:	Not determined
Relative density	:	Not determined

Water solubility	:	Soluble
Partition coefficient, n-octanol/water (log Pow)	:	Not available
Auto-inflammability temperature	:	Not available
Decomposition temperature	:	Not available
Viscosity	:	Not available
Explosive properties	:	Not available
Oxidizing properties	:	Not available
Solubility in other Solvents	:	Not available
Particle characteristics	:	Not available
	:	Not available

9.2 Other safety information

Information concerning to the classes of physical hazards

Not available

Other security characteristics

Not available

section 10 Stability and Reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

The product is stable when stored at recommended temperatures.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

Does not decompose when used for intended uses.

Additional information

Not available

section 11 Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity:

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Acute dermal toxicity:

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Acute inhalation toxicity:

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Skin corrosion/irritation:

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Serious eye damage/irritation:

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Skin sensitisation:

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Specific target organ toxicity (repeated exposure):

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Specific target organ toxicity (single exposure):

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Carcinogenicity:

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Reproductive toxicity:

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Germ cell mutagenicity:

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Sensitisation to the respiratory tract:

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

Additional information:

Not available

section 12 Ecological information

12.1 Toxicity

Based on available data, the classification criteria are not met.

Data for mixture:

Not available

Substances:

Not available

12.2 Persistence and degradability

The product has not been tested.

Data for mixture:

Not available

Substances:

Not available

12.3 Bioaccumulative potential

The product has not been tested.

Data for mixture:

Not available

Substances:

Not available

12.4 Mobility in soil

The product has not been tested.

Data for mixture:

Not available

Substances:

Not available

12.5 Results of PBT and vPvB assessment

According to Regulation (EU) 1907/2006, no substances are assessed as PBT or vPvB.

12.6 Endocrine disrupting properties

According to Regulation (EU) 2017/2100 or Regulation (EU) 2018/605, no substances are known to have endocrine disrupting properties.

12.7 **Other adverse effects**

Not available

Additional ecotoxicological information

Not available

section **13 Disposal considerations**

13.1 **Waste treatment methods**

Product/Packaging disposal:

Waste treatment options:

Appropriate disposal/Product:

Disposal practice must be in compliance with company, local, state and federal laws and regulations. If needed, Contact local, state or country environmental agency for specific rules.

Appropriate disposal/Package:

Non-contaminated packages must be recycled or disposed of.

Contaminated packing must be completely emptied and can be reused after proper cleaning. Packing which cannot be properly cleaned must be disposed of.

Dispose of waste according to applicable legislation.

section **14 Transport information**

14.1 **UN number**

The product is not hazardous according to the applicable transport regulations.

14.2 **UN proper shipping name**

Not regulated.

14.3 **Transport hazard class(es)**

Not regulated.

14.4 **Packing group**

Not regulated.

14.5 **Environmental hazards**

Not regulated.

14.6 **Special precautions for user**

Not regulated.

14.7 **Bulk shipping according to IMO instruments**

Not regulated.

section 15 Regulatory information

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

This SDS has been established in accordance with HazCom 2012.

15.2 Chemical Safety Assessment

Not available

Additional information

Not available

section 16 Other information

Abbreviations and acronyms

CAS: Chemical Abstract Service Number.

IATA: International Air Transport Association.

IMDG: International Maritime Dangerous Goods Code.

DPD Dangerous Preparation Directive.

UN number: United Nations number.

No EC: European Commission Number.

DOT: Department of Transportation.

HCS/HazCom: Hazard Communication.

Key literature references and sources for data

No data available.

The classification of the mixture is in accordance with the evaluation method described in HazCom 2012

The classification of the mixture is in accordance with the evaluation method described in HazCom 2012.

The classification of the mixture is in accordance with the evaluation method described in the GHS

Training advice

Refer to Sections 4, 5, 6, 7 and 8 of this safety data sheet.

Creation date: 06/27/2023

Version date: 01/25/2024

The information given in this Safety Data Sheet is based on our present knowledge and on European and national regulations. This Safety Data Sheet describes safety requirements relative to identified uses, it doesn't guarantee all the product properties particularly in the case of non identified uses. The product mustn't be used for any uses other than those identified under heading 1. Since the user's working conditions are not known by us, it is the responsibility of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.