

1) IDENTIFICATION OF SUBSTANCE / MIXTURE AND COMPANY / UNDERTAKING

1.1. Product identifiers:

Substance / Product name: **AMP Rapid Test SARS-CoV-2 Ag**
 Product code: RT2951 / RT2952
 REACH Registration No.: A registration number is not available for this mixture / product, as this mixture / product or its uses are exempted from registration and the annual tonnage does not require a registration.

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

1.2.1. Relevant identified uses In vitro diagnostic
 1.2.2. Uses advised against No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer: AMEDA Labordiagnostik GmbH
 Krenngasse 12
 A-8010 Graz / AUSTRIA
 Telephone: +43 316 69 80 69
 Fax: +43 316 69 80 69 12
 e-mail: office.graz@amp-med.com
 National Contact: Contact your local supplier

1.4. Emergency telephone number:

Toxication Information Center (Vienna)
 Emergency Number (00:00 to 24:00 h): +43-1-4064343

2) HAZARDS IDENTIFICATION

2.1. Classification of substance / mixture / product

Not hazardous according to Regulation (EC) No. 1272 / 2008

2.2. Label elements

No hazard labeling according to Regulation (EC) No. 1272 / 2008

2.3. Other hazards

- The usual hygienic measures taken when handling chemical materials are to be observed
- The usual Good Laboratory Practice guidelines are to be observed.

3) COMPOSITION / INFORMATION ON INGREDIENT

3.1. Product

| | | |
|---|-----------------|-----------------|
| Test cassette (individually foil wrapped) | RT2951: 10 pcs. | RT2952: 25 pcs. |
| Sterile swab (individually packed) | RT2951: 10 pcs. | RT2952: 25 pcs. |
| Extraction buffer | RT2951: 1pc. | RT2952: 2 pcs. |
| Extraction tube | RT2951: 10 pcs. | RT2952: 25 pcs. |
| Dropper tip | RT2951: 10 pcs. | RT2952: 25 pcs. |
| Tube holder | RT2951: 1 pc. | RT2952: 1 pc. |

3.2. Substances

Not applicable.

3.3. Mixtures

Extraction buffer (7 mL per bottle)

| Component | Concentration | Concentration limits | H Phrases | P Phrases | Classification (EC) No. 1278 / 2008 [CLP] | CAS No. |
|-------------|---------------|----------------------|-----------|-----------|---|-----------|
| TRIS buffer | 1.2 % | 1 - 5 % | n.a. | n.a. | non-dangerous | 77-86-1 |
| NaCl | 1,8% | 1.5 - 3 % | n.a. | n.a. | non-dangerous | 7647-14-5 |

| Component | Concentration | Concentration limits | H Phrases | P Phrases | Classification (EC) No. 1278 / 2008 [CLP] | CAS No. |
|--------------|---------------|----------------------|----------------------------|---|---|------------|
| Proclin 300 | 0.15 | 0.2 - 0.3 % | 302-312-314 317-332-411 | 273-280-301 303-304-305 310-312-338 340-351-353 361 | Acute toxic 4 Skin corr. 1A Skin sens. 1 Aquatic chronic 2 | n.a. |
| Twin 20 | 0.5 % | 0.4 - 0.6 % | n.a. | n.a. | non-dangerous | 9005-64-5 |
| Sodium Azide | 0.09% | 0.08 - 0.10 % | 301-310-318 370-372-401 | 260-262-264 270-273-280 301-305-307 310-311-321 330-338-351 352-361-405 501 | Acute toxic 2 Aquatic acute 1 Aquatic chronic 1 | 26628-22-8 |

This reagent does not contain any dangerous substances in reportable quantities.

4) FIRST AID MEASURES

Refers to extraction buffer only

4.1. Description of first aid measures

General notes: Move out of dangerous area. Consult a physician.
Following inhalation: Fresh air. Does not require medical control.
Following skin contact: Wash with plenty of water.
Following eye contact: Rinse immediately with plenty of water.
Following ingestion: Requires medical control.
Self-protection of the first aider: Not applicable.

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

No additional information available.

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

No additional information available.

5) FIREFIGHTING MEASURES

5.1. Extinguishing media

No restrictions.

5.2. Special hazards arising from the substance or the mixture

Hazardous combustion products: Dangerous decomposition is not anticipated.

5.3. Advice for firefighters

No additional information available.

6) ACCIDENTAL RELEASE MEASURES

Refers to extraction buffer only

6.1. Personal precautions, protective equipment and emergency procedures

In case of spillage, wash up with plenty of water. Wear gloves and protective clothing.
 Absorbent material : Special measures to limit damage are not necessary.

6.1.1 For non-emergency personnel

No additional information available.

6.1.2. For emergency responders

No additional information available.

6.2. Environmental precautions

No additional information available.

6.3. Methods and materials for containment and cleaning up**6.3.1. For containment**

No additional information available.

6.3.2. For cleaning up

No additional information available.

6.3.3. Reference to other sections

See section 7.

7) HANDLING AND STORAGE**7.1. Precautions for safe handling****Protective measures:**

Wear rubber gloves and protective clothing.

Measures to prevent fire:

No additional information.

Measures to prevent aerosol and dust generation:

No additional information.

Measures to protect the environment:

No additional information.

Advice on general occupational hygiene:

No additional information.

7.2. Conditions for safe storage, including any incompatibilities**Technical measures and storage conditions:**

Storage temperature 2° - 30 °C.

Packaging materials:

Cardboard box.

Requirements for storage rooms and vessels:

No specific requirements or restrictions. Keep away from food and beverages.

Storage class:**Further information on storage conditions:**

No additional information.

7.3. Specific end use(s)**Recommendations:**

Apart from the use mentioned in section 1.2 there is no alternative use.

8) EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters**

No data available.

8.2. Exposure controls**8.2.1. Appropriate engineering controls****Substance/mixture related measures to prevent exposure during identified uses:**

No additional information.

Structural measures to prevent exposure:

No additional information.

Organisational measures to prevent exposure:

No additional information.

Technical measures to prevent exposure:

No additional information.

8.2.2 Personal protection equipment:**8.2.2.1. Eye and face protection:**

Use of face mask and face shield recommended.

8.2.2.2. Skin protection:**Hand protection:** Wear disposable gloves.**Other skin protection:** Personnel protective equipment.**8.2.2.3. Respiratory protection:**

Use of face mask and face shield recommended.

8.2.2.4. Thermal hazards:

No additional information.

8.2.3. Environmental exposure controls:**Substance/mixture related measures to prevent exposure:**

No additional information.

Instruction measures to prevent exposure:

No additional information.

Organisational measures to prevent exposure:

No additional information.

Technical measures to prevent exposure:

No additional information.

9) PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties:**

| Property | Reagent R1 |
|--|-----------------|
| Appearance | Liquid |
| Colour | Colorless |
| Odour | Odorless |
| Odour threshold | Not determined |
| pH | 7.8 ± 0.1 |
| Melting / Freezing point | Not determined |
| Initial boiling point and boiling range | Not determined |
| Flash point | Not applicable. |
| Evaporation rate | Not determined |
| Flammability (solid, gas) | Not determined |
| Upper / lower flammability or explosive limits | Not explosive |
| Vapour pressure | Not determined |
| Vapour density | Not determined |
| Relative density | Not determined |
| Solubility(ies) | Soluble |
| Partition coefficient: n-octanol / water | Not determined |
| Auto-ignition temperature | Not determined |
| Decomposition temperature | Not determined |
| Viscosity | Not determined |
| Explosive properties | Not explosive |
| Oxidizing properties | Not determined |

9.2. Other information

No additional information available.

10) STABILITY AND REACTIVITY

10.1. Reactivity

No available data.

10.2. Chemical stability

Stable under recommended storage conditions during the entire shelf life.

10.3. Possibility of hazardous reactions

Not known if used appropriately.

10.4. Conditions to avoid

Strong acids, strong oxidising agents and high temperatures.

10.5. Incompatible materials

Information not available.

10.6. Hazardous decomposition products

Not known if used properly.

11) TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Substances: Not applicable.

Mixtures: Not applicable.

12) ECOLOGICAL INFORMATION

12.1. Toxicity

Not applicable.

12.2. Persistence and degradability

Ingredients are not expected to be resistant to biodegradation.

12.3. Bio-accumulative potential

No available data.

12.4. Mobility in soil

The product is freely miscible in water.

12.5. Results of PBT and vPvB assessment

No available data.

12.6. Other adverse effects

Not known.

13) DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Test cassette and sample must be disposed off in compliance with local legislation.

14) TRANSPORT INFORMATION

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packaging group

Not applicable.

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for users

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and IBC Code

This product is not subject to current regulations for transportation of hazardous substances.

15) REGULATORY INFORMATION

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

The Safety Data Sheet is in compliance with the requirements and guidance of Regulation (EU) 453 / 2010.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out by the supplier for this mixture.

16) OTHER INFORMATION

- I. Indication of changes:
First revision according to Regulation (EU) 453 / 2010.
- II. Relevant H-phrases and P-phrases:
Not applicable
- III. Training advice:
The usual Good Laboratory Practice guidelines are to be observed.
- IV. Further information:
This product is intended For *in vitro* diagnostic use only.

The information above is believed to be correct, but does not purport to be all-inclusive and is to be used as a guideline only. AMEDA Labordiagnostik GmbH shall not be held liable for any damage resulting from the mishandling of the product described in this document.