



Abbott

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

This document contains SDS for the following kit components: Device

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name	Panbio™ COVID-19 Ag Rapid Test Device
Reference No.	41FK10, 41FK11, 41FK20, 41FK21, 41FK31, 41FK41
Identification of the product:	See section 3.
Index Number:	Not available.
REACH registration NO.:	Not available.

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

1.2.1 Identified use(s)	Panbio™ COVID-19 Ag Rapid Test Device for the use as in vitro diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen in humans.
1.2.2 Uses advised against:	Not available.

1.3 Details of the supplier of the safety data sheet

Company Identification	Abbott Rapid Diagnostics Jena GmbH Orlaweg 1 D-07743 Jena - Germany
Telephone	+49-(0)3641-3111-444
E-Mail (competent person)	pima82.support@alere.com

1.4 Emergency telephone number

Emergency Phone No.	+49-(0)3641-3111-444 EU-wide emergency number: 112
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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.1 Classification:

The mixture is classified as following according to REGULATION (EC) NO 1272/2008:

REGULATION (EC) No. 1272/2008	
Hazard classes/Hazard categories	Hazard codes
N/A	N/A

2.2 Label elements

Hazard Pictograms	No hazard Pictogram is used.
Signal Word(S)	No signal word is used.
Hazard Statement	Not applicable.
Precautionary Statement	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures

Description:	Sodium azide
Dangerous components:	

Chemical Name	CAS No.	EC No.	REACH Registration No.	Classification code: Hazard Statement(s)	Concentration %W/W
Sodium azide	26628-22-8	247-852-1	-	Acute Tox. 2, H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	0.01517



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3.3 Additional Information

Each device is packaged in a foil pouch.

SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

General information

No general information.

Inhalation

When exposed to large amounts of steam and mist, move to fresh air. Take specific treatment if needed.

Skin Contact

Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash contaminated clothing thoroughly before re-using.

Eye Contact

Do not rub your eyes. Immediately flush eyes with plenty of water for at least 15 minutes and call a doctor/physician.

Ingestion

Please be advised by doctor whether induction of vomit is demanded or not. Rinse your mouth with water immediately.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of the immediate medical attention and special treatment needed

Notify medical personnel of contaminated situations and have them take appropriate protective measures.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media

Dry chemical, carbon dioxide, regular foam extinguishing agent, spray

Unsuitable extinguishing media

Avoid use of water jet for extinguishing

5.2 Special hazards arising from the substance or mixture

Not available.

5.3 Advice for fire-fighters

Cool containers with water until well after fire is out. Keep unauthorized personnel out. Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank. Notify your local firestation and inform the location of the fire and characteristics hazard. Keep containers cool with water spray. Use fire fighting procedures suitable for surrounding area.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Protective equipment: Wear proper protective equipment.
Emergency procedures: Not applicable. If required, notify relevant authorities according to all applicable regulations.

For emergency responders

Wear proper personal protection as indicated in Section 8 and avoid skin contact and inhalation. Must work against the wind, let the upwind people to evacuate. Do not touch spilled material. Stop leak if you can do it without risk. Move container to safe area from the leak area.



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|---|--|
| 6.2 Environmental precautions | Prevent runoff and contact with waterways, drains or sewers. If large amounts have been spilled, inform the relevant authorities. Avoid dispersal of spilt material and runoff and contact with waterways, drains and sewers. If large spills, advise emergency services. |
| 6.3 Methods and material for containment and cleaning up | Don't use a brush or compressed air for cleaning surfaces or clothing. Clean up all spills immediately. No smoking, flame or ignition sources. Stop leak if safe to do so.
Large spill: Stay upwind and keep out of low areas. Dike for later disposal. Notify the central and local government if the emission reaches the standard threshold. Disposal of waste shall be in compliance with the applicable law and regulations. Appropriate container for disposal of spilled material collected.
Small liquid-state spills: Appropriate container for disposal of spilled material collected. Put the spilled material in an appropriate container and clean the contaminated area. |
| 6.4 Reference to other sections | See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment. |
| 6.5 Additional information | See Section 13 for information on disposal.
Slippery when spilt. |

SECTION 7: HANDLING AND STORAGE

- | | |
|---|--|
| 7.1 Precautions for safe handling
Protective measures

Advice on general occupational hygiene | Avoid contact with incompatible materials. Handle only in a well-ventilated place. Do not handle until all safety precautions have been read and understood. |
| 7.2 Conditions for safe storage, including any incompatibilities | Store in cool, dry and well ventilated place. Do not apply direct heat. Store according to current laws and regulations. Avoid direct sunlight. Prevent static electricity and keep away from combustible materials or heat sources. |
| 7.3 Specific end use(s) | See Section 1 for information on 1.2 Relevant identified uses. |

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- | | |
|---|---|
| 8.1 Control parameters
8.1.1 Occupational Exposure Limits
8.1.2 Additional exposure limits under the conditions of use | Not available.
Personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. |
| 8.1.3 DNEL/DMEL and PNEC-Values | Not available. |
| 8.2 Exposure controls
8.2.1 Appropriate engineering controls | Business owner is recommended to maintain below recommended exposure limits for the working place with general exhaust of gas/vapour/mist/fume. |
| 8.2.2 Personal protection equipment
Eye/face protection

Hand protection
Body protection
Respiratory protection | Wear primary eye protection such as splash resistant safety goggles with a secondary protection face shield. Provide an emergency eye wash station and quick drench shower in the immediate work area.
Wear appropriate gloves.
Skin protection: Wear appropriate clothing.
Respiratory protection is ranked in order from minimum to maximum. |



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Consider warning properties before use.
Under conditions of frequent use or heavy exposure, respiratory protection may be needed.
Dust, mist, fume-purifying respiratory protection.
Air-purifying respirator with high-efficiency particulate filtering.
Any respiratory protection with a electromotion fan (for dust, mist, fume-purifying).
Self-contained breathing apparatus with a corpuscle filter of high efficiency.
For Unknown Concentration or Immediately Dangerous to Life or Health: Any supplied air respirator with full facepiece and operated in a pressure-demand or other positive pressure mode in combination with a separate escape supply. Any self contained breathing apparatus with a full facepiece.

Thermal hazards

No special protective equipment required.

8.2.3 Environmental Exposure Controls

Do not let product enter drains. For ecological information refer to section 12.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Solid.
Colour	Not available.
Odour	Not available.
Odour Threshold (ppm)	Not available.
pH (Value)	Not available.
Melting Point (°C) / Freezing Point (°C)	Not available.
Boiling point/boiling range (°C):	Not available.
Flash Point (°C)	Not available.
Evaporation rate (BA = 1)	Not available.
Flammability (solid, gas)	Not available.
Explosive limit ranges	Not available.
Vapour Pressure (Pascal)	Not available.
Vapour Density (Air=1)	Not available.
Density (g/ml)	Not available.
Solubility (Water)	Not available.
Solubility (Other)	Not available.
Partition Coefficient (n-Octanol/water)	Not available.
Auto Ignition Temperature (°C)	Not available.
Decomposition Temperature (°C)	Not available.
Viscosity (mPa.s)	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.
Molecular Formular	Not available.
Molecular Weight	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

This material is stable under recommended storage and handling conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerization will not occur.



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- 10.4 Conditions to avoid** Avoid the contact with ncompatible materials and condition. Avoid the accumulation of electrostatic charges, heating, flames and hot surfaces.
- 10.5 Incompatible materials** Not available.
- 10.6 Hazardous Decomposition Product(s)** May emit flammable vapour if involved in fire.

▶ SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1 Information on toxicological effects**
- 11.1.1 Substances**
Not applicable.
- 11.2 Information on toxicological effects**
- Acute toxicity
 - LD50(Oral): Product (ATEmix) : Not available
[Water] : LD50 > 90000 mg/kg Rat (KOSHA),
[Sodium azide] : LD50 = 5 ~ 50 mg/kg
 - LD50(Dermal): Not available.
 - LC50(Inhalation): Not available.
 - Skin corrosion/irritation Not available.
 - Serious eye damage/irritation Not available.
 - Respiratory/skin sensitization Not available.
 - Germ cell mutagenicity Not available.
 - Carcinogenicity ACGIH: [Sodium azide]: A4
 - Reproductive toxicity Not available.
 - STOT - single exposure Not available.
 - STOT - repeated exposure Not available.
- 11.2 Other information** Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Acute toxicity		Time	Species	Evaluation	Remarks
LC50	Sodium azide	96h	Fish	≤1 mg/L	N/A
EC50	Sodium azide	48h	Invertebrate	≤1 mg/L	N/A
EC50	Sodium azide	72 or 96h	Algae	≤1 mg/L	N/A

12.2 Persistence and degradability

- 12.2.1 Persistence**
- [Water] : log Kow = -1.38
- 12.2.2 Degradability**
- Not available
- 12.3 Bioaccumulative potential**
- Not available
- 12.4 Mobility in soil**
- Not available
- 12.5 Results of PBT and vPvB assessment**
- Not available
- 12.6 Other adverse effects**
- Not available



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SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1 Waste treatment methods** Stabilization and minimization treatment by incineration or similar method can be applied, if more than two kinds of designated wastes are in mixture state and it is impractical to separate them. Oil water separation technology shall be applied as pre-waste treatment if it is applicable. It shall be treated by incineration. Dispose of waste in accordance with all applicable laws and regulations.
- Product/ Packaging disposal:** If empty container retains product residues, all label precautions must be observed. Dispose according to national or local regulations.
- European waste catalogue:** 18 01 03.

SECTION 14: TRANSPORT INFORMATION

	Land transport (ADR/RID)	Sea transport (IMDG)	Air transport (ICAO/IATA)
UN-Number	Not regulated	Not regulated	Not regulated
UN Proper shipping name	Not regulated	Not regulated	Not regulated
Transport hazard Class	Not regulated	Not regulated	Not regulated
Packaging group	Not regulated	Not regulated	Not regulated
Environmental hazards	No	No	No
Special precautions for user	See section 2.2	See section 2.2	See section 2.2
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not regulated	Not regulated	Not regulated

SECTION 15: REGULATORY INFORMATION

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- | | |
|--|--|
| Relevant information regarding authorization | Not applicable. |
| Relevant information regarding restriction | Not applicable. |
| Other EU regulations | In Vitro diagnostics medical devices directive 98/79/EC. |
| Other National regulations | Not applicable. |
- 15.2 Chemical Safety Assessment has been carried out?** No.

▶ SECTION 16: OTHER INFORMATION

- Indication of changes** The Safety Data Sheet has been reviewed and the data therein were revised and laid out according the requirements of the Commission Regulation (EC) No. 1907/2006
- Training instructions** Not applicable.
- Further information** The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered. This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



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Notice to reader

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

LEGEND

Classification code:

Acute Tox. 2	Acute toxicity, Category 2.
Aquatic Acute 1	Acute aquatic hazard. Acute 1.
Aquatic Chronic 1	Long-term aquatic hazard, Chronic 1.
LD ₅₀ Oral	Median lethal dose. The dose causing 50 % lethality when given orally.
LC50	Median lethal concentration. The concentration causing 50 % lethality.
EC50	Effective concentration (50%).
ACGIH A4	American Conference of Governmental Industrial Hygienists (ACGIH) Group A4

Hazard statement(s)

- H300: Fatal if swallowed.
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long lasting effects.

References:

Raw material safety data sheets.

Additional Information

Reason for update:	Product reference numbers updated.
Supersedes:	Version 3.0

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