



Safety Data Sheet (SDS)

According to Regulation (EC) No 1907/2006 (REACH), Annex II(COMMISSION REGULATION (EU) No 2015/830)

Panbio™ COVID-19 Ag Rapid Test Device

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

1.1. Product identifier

Trade name/designation : Panbio™ COVID-19 Ag Rapid Test Device, Assay diluent
Cat. No. : 41FK10, 41FK11, 41FK15

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

1.2.1. Relevant identified uses

- Not available

1.2.2. Uses advised against

- Not available

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier : Abbott Diagnostics Korea Inc.
Address : 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 17099, Republic of Korea
Telephone : 82 (31) 899-2800
Email : guiyoung.kim@abbott.com

1.4. Emergency telephone number

EU-wide emergency number : 112

See section 16.6 for the list of telephone number of National Helpdesks in the European Economic Area.

SECTION 2: HAZARD IDENTIFICATION

2.1. Classification of the substance/mixture

2.1.1. Classification according to Regulation (EC) No 1272/2008 [CLP]

- Not applicable

2.2. Label elements

2.2.1. Labelling according to Regulation (EC) No 1272/2008 [CLP]

* Hazard Pictogram(s)

- Not applicable

* Signal word : Not applicable

* Hazard statement(s)

- Not applicable

* Precautionary statement(s)

1) Prevention

- Not applicable

2) Response

- Not applicable

3) Storage

- Not applicable

4) Disposal

- Not applicable

2.3. Other hazards

- Not available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**3.1. Substances**

- Not applicable

3.2. Mixtures

Name	EC No.	CAS No.	REACH registration No.	% [weight]	Classification [1272/2008/EC]
Water	231-791-2	7732-18-5	-	94.7349951	Not classified
Tricine	227-193-6	5704-04-1	-	3.525	Not classified
Sodium chloride	231-598-3	7647-14-5	-	1.15	Aquatic Acute 1, H400 Repr. 2, H361 Muta. 1B, H340 STOT RE 2, H373
Sorbitan, monododecanoate, poly(oxy-1,2-ethanedijl) derivs.	-	9005-64-5	-	0.492	Eye Irrit. 2, H319 Skin Irrit. 2, H315
Sodium azide	247-852-1	26628-22-8	-	0.098	Acute Tox. 2, H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)	-	55965-84-9	-	0.0000049	Acute Tox. 3, H301 Acute Tox. 2, H310 Acute Tox. 2, H330

SECTION 4: FIRST AID MEASURES**4.1. Description of first aid measures****General**

- 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 any immediate medical attention and special treatment needed

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

SECTION 5: FIREFIGHTING 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

Hazardous combustion products

- Not available

5.3. Advice for firefighters

- Move containers from fire area, if you can do without the risk.
- 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.
- Vapor or gas is burned at distant ignition sources can be spread quickly.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

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

6.1.2. For emergency responders

- Ventilate closed spaces before entering.
- Must work against the wind, let the upwind people to evacuate.
- Move container to safe area from the leak area.
- Do not direct water at spill or source of leak.

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

6.3.1. For containment

- Prevent, by any means available, spillage from entering drains or water course.
- No smoking, flame or ignition sources.
- Stop leak if safe to do so.

6.3.2. For cleaning up

- Large spill : Stay upwind and keep out of low areas. Dike for later disposal.
- Notify the central and local government if the emission reach the standard threshold.
- Disposal of waste shall be in compliance with the Wastes Control?Act
- Appropriate container for disposal of spilled material collected.
- Small leak: sand or other non-combustible material, please let use absorption.
- Wipe off the solvent.
- Dike for later disposal.

6.3.3. Other information

- Slippery when spilt.

6.4. Reference to other sections

- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for information on disposal.

SECTION 7: HANDLING AND STORAGE**7.1. Precautions for safe handling**

- Since emptied containers retain product residue(vapor, liquid, solid) follow all MSDS and label warnings even after container is emptied.
- Refer to Engineering controls and personal protective equipment.
- Dealing only with a well-ventilated place.
- Operators should wear antistatic footwear and clothing.
- Do not inhale the steam prolonged or repeated.

7.2. Conditions for safe storage, including any incompatibilities

- Save in cool, dry and well ventilated place.
- Do not use damaged containers.
- Do not apply any physical shock to container.
- No open fire.
- 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****European Union (EU) Commission Directive 2006/15/EC (IOELVs)**

- Not available

European Union (EU) Commission Directive 2006/15/EC (IOELVs) - Skin

- Not available

8.1.2. Recommended Monitoring Procedures

- 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/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. Individual protection measures, such as personal protective equipment**Hand protection**

- Wear appropriate glove.

Eye 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.

Respiratory Protection

- Respiratory protection is ranked in order from minimum to maximum.
- Consider warning properties before use.
- Any chemical cartridge respirator with organic vapor cartridge(s).
- Any chemical cartridge respirator with a full facepiece and organic vaporcartridge(s).
- Any air-purifying respirator with a full facepiece and an organic vapor canister.
- 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.
- Under conditions of frequent use or heavy exposure, Respiratory protection may be needed.

Skin protection

- Wear appropriate clothing.

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(State)	Liquid
Appearance(Color)	colorless
Odor	Not available
Odor threshold	Not available
pH	Not available
Melting point/Freezing point	Not available
Initial boiling point and boiling range	Not available
Flash point	Not available
Evaporation rate	Not available
Flammability(solid, gas)	Not available
Upper/Lower Flammability or explosive limits	Not available
Vapour pressure	Not available
Vapour density	Not available
Relative density	Not available
Solubility	Not available
Partition coefficient of n-octanol/water	Not available
Autoignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Explosive properties	Not available
Oxidising properties	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.

10.4. Conditions to avoid

- Avoid contact with incompatible materials and condition.
- Avoid : Accumulation of electrostatic charges, Heating, Flames and hot surfaces

10.5. Incompatible materials

- Not available

10.6. Hazardous decomposition products

- May emit flammable vapour if involved in fire.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Acute toxicity****- Oral**

- Product (ATEmix) : >5000mg/kg
- [Water] : LD50 > 90000 mg/kg Rat (KOSHA)
- [Sodium chloride] : LD50 = 3000 mg/kg Rat (IUCLID)
- [Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.] : LD50 = 36700 mg/kg Rat
- [Sodium azide] : LD50 = 5 ~ 50 mg/kg
- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] : LD50 = 50 ~ 300 mg/kg

- Dermal

- Product (ATEmix) : >5000mg/kg
- [Sodium chloride] : LD50 > 10000 mg/kg Rabbit (Thomson Micromedex)
- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] : LD50 = 87.12 mg/kg Rabbit (ECHA)

- Inhalation

- Product (ATEmix) : Not available
- [Sodium chloride] : Dust LC50 > 10.5 mg/l 4 hr Rat (Thomson Micromedex)
- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] : LC50 = 0.5 ~ 2.0 mg/L

11.2. Skin corrosion/irritation

- Not available

11.3. Serious eye damage/irritation

- Not available

11.4. Respiratory sensitization

- Not available

11.5. Skin sensitization

- Not available

11.6. Germ cell mutagenicity

- Not available

11.7. Carcinogenicity**- IARC**

- Not available

- OSHA

- Not available

- ACGIH

- [Sodium azide] : A4

- NTP

- Not available

- EU CLP

- Not available

11.8. Reproductive toxicity

- Not available

11.9. Specific target organ toxicity(single exposure):

- Not available

11.10. Specific target organ toxicity(repeated exposure):

- Not available

11.11. Aspiration hazard

- Not available

SECTION 12: ECOLOGICAL INFORMATION**12.1. Toxicity****12.1.1. Fish**

- [Sodium chloride] : LC50 5840 mg/ℓ 96 hr *Lepomis macrochirus* (Reliability 1, ASTM E729)
- [Sodium azide] : LC50(96hr) ≤ 1 (mg/L)
- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] : LC50(96hr) 0.19 mg/L *Oncorhynchus mykiss* (ECHA)

12.1.2. Invertebrate

- [Tricine] : LC50 9822.517 mg/ℓ 48 hr Other (Estimate)
- [Sodium chloride] : LC50 874 mg/ℓ 48 hr *Daphnia magna* (Reliability 2, Standard methods for the Examination of Water and Waste Water)
- [Sodium azide] : EC50(48hr) ≤ 1 (mg/L)
- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] : EC50(48hr) 0.18 mg/L *Daphnia magna* (ECHA)

12.1.3. Algae

- [Tricine] : EC50 867.619 mg/ℓ 96 hr Other (Estimate)
- [Sodium chloride] : EC50 0.0269 mg/ℓ 72 hr ((*Pseudokirchneriella subcapitata*, Growth Rate) Reliability 1, OECD Guideline 201, GLP)
- [Sodium azide] : ErC50(72 or 96hr) ≤ 1 (mg/L)
- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] : ErC50(72hr) 0.0199 mg/L *Skeletonema costatum* (ECHA)

12.2. Persistence and degradability**12.2.1. Persistence**

- [Water] : log Kow = -1.38
- [Tricine] : log Kow -2.870 (NLM)
- [Sodium chloride] : log Kow -0.46 (Estimate)
- [Sorbitan, monododecanoate, poly(oxy-1,2-ethanediy) derivs.] : log Kow -2.03 (Estimate)

12.2.2. Degradability

- Not available

12.3. Bioaccumulative potential**12.3.1. Bioaccumulation**

- [Tricine] : BCF 3.162 (Estimate)
- [Sodium chloride] : BCF 3.162 (Estimate)
- [Sorbitan, monododecanoate, poly(oxy-1,2-ethanediy) derivs.] : BCF 3.16 (Estimate)

12.3.2. Biodegradability

- [Tricine] : BIOWIN 6 (Estimate)
- [Sorbitan, monododecanoate, poly(oxy-1,2-ethanediy) derivs.] : (non-biodegradable, not degraded and has a high potential to accumulate in vivo) (EPI Suite)

12.4. Mobility in soil

- [Tricine] : Koc -2.298
- [Sorbitan, monododecanoate, poly(oxy-1,2-ethanediy) derivs.] : Koc = 239700000 (Can be adsorbed in the soil, Estimates)

12.5. Results of PBT and vPvB assessment

- Not available

12.6. Other adverse effects

- Not available

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
- Anyone with business license number who generates industrial wastes shall treat the waste by him/herself or by entrusting to the legal entities who treat the wastes, recycle the wastes of others or install and operate the waste treatment facilities according to the Wastes Control Act
- Dispose of waste in accordance with all applicable laws and regulations.

SECTION 14: TRANSPORT INFORMATION**14.1. UN No.****14.1.1. UN No. (ADR/RID/ADN)**

- Not applicable

14.1.2. UN No. (IMDG CODE/IATA DGR)

- Not applicable

14.1.3. UN No. (ICAO)

- Not applicable

14.2. UN proper shipping name

- Not applicable

14.3. Transport hazard class(es)**14.3.1. ADR/RID/ADN Class**

- Not applicable

14.3.2. ADR/RID/ADN Class

- Not available

14.3.3. ADR Label No.

- Not applicable

14.3.4. IMDG Class

- Not applicable

14.3.5. ICAO Class/Division

- Not applicable

14.3.6. Transport Labels

- Not applicable

14.4. Packing group**14.4.1. ADR/RID/ADN Packing group**

- Not applicable

14.4.2. IMDG Packing group

- Not applicable

14.4.3. ICAO Packing group

- Not available

14.5. Environmental hazards

- Not applicable

14.6. Special precautions for user

- Local transport follows in accordance with Dangerous goods Safety Management Law.
- Package and transport follow in accordance with Department of Transportation (DOT) and other regulatory agency requirements.
- EmS FIRE SCHEDULE : Not available
- EmS SPILLAGE SCHEDULE : Not available
- Air transport(IATA): Not subject to IATA regulations.

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

- Not applicable

SECTION 15: REGULATORY INFORMATION

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

15.1.1. Europe regulatory

15.1.1.1 REACH Restricted substance under REACH

- Not applicable

15.1.1.2 REACH Substances subject to authorization under REACH

- Not applicable

15.1.1.3 REACH SVHC

- Not applicable

15.1.1.4 Europe PBT

- Not applicable

15.1.1.5 European Union (EU) Transport of Dangerous Goods by Road - Dangerous Goods List

- Not applicable

15.2. Chemical Safety Assessment

- Not conducted

SECTION 16: OTHER INFORMATION

16.1. Indication of changes

- The Safety Data Sheet has been reviewed and the data therein were revised and laid out according to the requirements of the Commission Regulation (EC) No. 1907/2006

16.2. Abbreviations and acronyms

- 1272/2008 CLP : Classification, Labelling and Packaging regulation.
- REACH : Registration, Evaluation and authorisation of chemical substances.
- DNEL : Derive no effects level
- PNEC : Predicted no effect concentration

16.3. Key literature references and sources for data

- This Safety Data Sheet was compiled with data and information from the following sources: RTECS, ECOSAR, HSDB, SIDS SIAP, ChemWATCH, CESAR, Chemical DB

16.4. Classification procedure

- The mixture classification has been derived based on the classification of the individual components in accordance with the rules set out in Regulation (EC) No 1272/2008 (CLP) as well as the translation tables in Annex VII to the same regulation.

16.5. Training advice

- Not applicable

16.6. 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.
- Contact National Helpdesks, List of Telephone Numbers : AUSTRIA (Vienna Wien) +43 1 515 61 0, BELGIUM (Brussels Bruxelles) +32 070 245 245, BULGARIA (Sofia) +359 2 9888 205, Croatia +385 1 2348 342 CZECH REPUBLIC (Prague Praha) +420 224 919 293 or +420 224 915 402, DENMARK (Copenhagen) 82 12 12 12, ESTONIA (Tallinn) 112, FINLAND (Helsinki) +358 9 471 977, FRANCE (Paris) +33 1 45 42 59 59, GERMANY (Berlin) +49 30 19240, GREECE (Athens Athinai) +30 210 77 93 777, HUNGARY (Budapest) +36 80 201 199, ICELAND (Reykjavik) +354 543 2222 or 112, IRELAND (Dublin) +353 1 8379964 or +353 1 809 2166, ITALY (Rome) +39 06 305 4343, LATVIA (Riga) 112 or +371 6704 2473, LITHUANIA (Vilnius) +370 5 236 20 52 or +370 687 53378, Luxembourg +352 70 245 245, MALTA +356 2122 4071, NETHERLANDS (Bilthoven) +31 30 274 88 88, NORWAY (Oslo) 22 591300, POLAND (Gdansk) +48 58301 65 16 or +48 58 349 2831, PORTUGAL (Lisbon Lisboa) 808 250 143, ROMANIA (Bucharest) +40 21 3183606 SLOVAKIA (Bratislava) +421 2 54 77 4166, SLOVENIA (Ljubljana) + 386 41 650 500, SPAIN +34 91 562 04 20(spanish language) or +34 91 768 98 00(You can request to be served in English), SWEDEN (Stockholm) 112 or +46 10 456 6700 (mon-fri 9.00-17.00), UNITED KINGDOM (London) 112 or 0845 4647 (NHS Direct).