SAFETY DATA SHEET	Document No.	BT-MSDS403
	Rev. No.	11
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Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier: AFIAS FSH / SMFP-5

1.2. Relevant identified uses of the substance or mixture and uses advised against
Recommended use: In vitro diagnostic Medical Device
Restricted use: For in vitro diagnostic use only.

1.3. Details of the supplier of the safety data sheet
Manufacturer: Boditech Med Inc. Address: 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea

1.4. Emergency Phone No.
Manufacturer +82-33-243-1400(cej1@boditech.co.kr)

Section 2. Hazard Identification

2.1. Classification of the substance or mixture

GHS classification	No data available
IMDG Code	No data available

2.2. Label elements

Symbols	No data available
Signal word	No data available
Hazard statements	No data available

2.3. Other hazards

NEPA	No data available

Section 3. Composition/Information on Ingredients

3.1. Substance

3.2. Mixtures

[Cartridge]

	Component	Synonyms	Classification No.	Amount
Housing	2-Propenenitrile polymer with 1,3-butadiene and ethenylbenzene	ABS	9003-56-9	> 95%
Test Strip	No data available	No data available	No data available	No data available
Detector Tube	No data available	No data available	No data available	No data available
Detector Diluent	No data available	No data available	No data available	No data available

[ID chip]

Component	Synonyms	Classification No.	Amount
2-Propenenitrile polymer with 1,3-butadiene and ethenylbenzene	ABS	9003-56-9	No data available

The product is a mixture, and each substance is not classified as a hazardous substance according to Regulation (EC) No 1907/2006(Annex XIV Annex XVII), Regulation (EC) No 1272/2008(Annex VI). According to Annex II of Regulation (EC) No 1907/2006, substances below 0.1% are not listed.

Section 4. First Aid Measures

4.1. Description of first aid measures

- In case of eye contact: Remove the individual from the source of exposure. Rinse the affected area with copious amounts of water for at least 15 minutes. If irritation or signs of toxicity occur, seek medical attention immediately.
- In case of skin contact: Remove the individual from the source of exposure. Wash the affected area thoroughly with soap and water. If irritation or signs of toxicity occur, seek medical attention immediately.
- If inhaled: Get medical attention immediately. Move the individual to fresh air. If the person is not breathing, administer cardiopulmonary resuscitation (CPR). If breathing is difficult, provide oxygen and continue to monitor the individual.
- If swallowed: If irritation or signs of toxicity occur, seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed
The following symptoms may occur: Irreversible eye damage.
Medical conditions that may be aggravated by exposure include pre-existing eye disorders and hypersensitivity.

4.3. Indication of any immediate medical attention and special treatment needed
This material should be considered potentially infectious and handled accordingly.

Section 5. Fire Fighting Measures

5.1. Extinguishing media
Suitable extinguishing agents including carbon dioxide (CO_2), water spray, or regular foam

5.2. Special hazards arising from the substance or mixture
The material is non-flammable; however, corrosive or toxic gases and fumes may be released during a fire. Inhalation may be hazardous.

5.3. Advice for firefighters
- Firefighters and rescuers should wear appropriate personal protective equipment (PPE). If there is no immediate danger, remove containers from the fire area. Although the material is non-flammable, corrosive or toxic gases and fumes may be released during a fire. Inhalation may be hazardous.
- Use fire-resistant and chemical-resistant protective equipment.

Section 6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures
- Stop the leak if it is not hazardous to do so.
- Do not come into contact with the released material without proper protective equipment.
- Avoid contact with incompatible conditions and materials.
- Do not breathe dust, fumes, gas, mist, vapours, or spray.

6.2. Environmental precautions
No data available

6.3. Methods and material for containment and cleaning up
After absorbing the spilled material, clean the affected area thoroughly with detergent and water.

6.4. Reference to other sections
No data available

Section 7. Handling and Storage

7.1. Precaution for safe handling
- Avoid skin friction.
- Avoid conditions and materials that may cause fire or ignition.

7.2. Conditions for safe storage, including any incompatibilities
- Be aware of conditions and materials that should be avoided.
- Store the container tightly closed in a well-ventilated area.

- Store at low temperature.

7.3. Specific end use(s)

Use chemical-resistant protective goggles, gloves, clothing, and a mask.

Section 8. Exposure controls/Personal protection

8.1. Control parameters

Chemical exposure limits: No data available

Biological exposure limits: No data available

8.2. Exposure controls

- Engineering Controls: Adequate ventilation should be provided to maintain airborne concentrations. Local exhaust ventilation is recommended where appropriate.
- Personal protective equipment

Respiratory protection	Use chemical-resistant respiratory equipment appropriate for the level of exposure.
Hand protection	Wear chemical-resistant protective gloves.
Eye protection	Wear chemical-resistant safety goggles or face shield.
Skin and body protection	Wear chemical-resistant protective clothing.

Section 9. Physical and Chemical properties

9.1. Information on basic physical and chemical properties

Property	Value / Description	Remarks
Appearance	Clear liquid contained in a plastic vial/tube; small volume	
Physical state	Liquid (inside plastic container).	
Odor	Odorless	
Odor threshold	Not applicable	
pH	Approximately neutral (pH ~7).	
Melting point / Freezing point	~0 °C (water-based solution).	
Boiling point / Boiling range	~101 °C (water-based solution).	
Flash point	Not applicable	
Evaporation rate	Similar to water.	
Flammability (solid, gas)	No data available	
Upper / Lower flammability or explosive limits	Not determined	
Vapor pressure	Not applicable	
Vapor density	Similar to water.	
Relative density	~1.0 (water-like).	
Solubility(ies)	Completely soluble in water.	
Partition coefficient (n-octanol/water)	Not applicable	
Auto-ignition temperature	No data available	
Decomposition temperature	No data available	
Viscosity	Low viscosity; similar to water.	
Explosive properties	Not explosive	
Oxidizing properties	Not oxidizing	

9.2. Other information

No data available

Section 10. Stability and reactivity

10.1. Reactivity
No data available

10.2. Chemical stability
Stable under recommended storage and handling conditions.

10.3. Possibility of hazardous reactions
No data available

10.4. Conditions to avoid
Avoid excessive heat, open flames, and ignition sources.

10.5. Incompatible materials
No data available

10.6. Hazardous decomposition products
No data available
No data available

Section 11. Toxicological Information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicological parameter	Result
Routes of exposure	No data available
Acute toxicity	No data available
Skin corrosion/Irritation	No data available
Serious eye damage/Eye irritation	No data available
Respiratory/Skin sensitization	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	No data available
Reproductive toxicity	No data available
Specific target organ toxicity (single exposure)	No data available
Specific target organ toxicity (repeated exposure)	No data available
Aspiration hazard	No data available

11.2. Information on other hazards
No data available

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. Endocrine disrupting properties
No data available
12.7. Other adverse effects
No data available

Section 13. Disposal Considerations

13.1. Waste treatment methods
Dispose of the material in accordance with the Waste Management Act and applicable local regulations.

Section 14. Transport information

14.1. UN number or ID number
No data available
14.2. UN proper shipping name
No data available
14.3. Transport hazard class(es)

IMDG Code	No data available
DRF	No data available
RID	No data available
ADR	No data available
ADN	No data available
IATA	Not regulated as dangerous goods

Not a dangerous good under DOT, IATA, ADR, IMDG, or RID

14.4. Packing group
No data available
14.5. Environmental hazards
No data available
14.6. Special precautions for user
No data available
14.7. Maritime transport in bulk according to IMO instruments
No data available

Section 15. Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
This product is subject to the following regulations:
Republic of Korea
- Industrial Safety and Health Act
- Hazardous Materials Safety Control Act
- Korea Toxic Chemical Control Act

European Union
- Annex II of Regulation (EU) 2020/878
- Regulation (EC) No 1907/2006 (REACH)
- Regulation (EC) No 1272/2008 (CLP)

15.2. Chemical safety assessment

A chemical safety assessment has not been carried out.

Section 16. Other Information

References

1) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
2) Regulation (EC) No 1272/2008 - classification, labelling and packaging of substances and mixtures (CLP)

Disclaimer

1) The information provided herein is believed to be accurate as of the date of issue. It is intended for guidance on safe use and handling but does not constitute a warranty. Users are responsible for compliance with applicable regulations. The supplier assumes no liability for damages resulting from the use of this information.