

Document No.	BT-MSDS482
Rev. No.	00
Rev. Date	2022. 10. 18

I. General Information

- A. Product Name/Catalogue Number
 - : AFIAS D-Dimer Neo / SMFP-129
- B. Recommended use of the chemical and restriction on use
 - Recommended use: In vitro diagnostic Medical Device
 - Restriction on use: For in vitro diagnostic use only.
- C. Manufacturer
 - : Boditech Med Inc.
- D. Address
 - : 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea
- E. Emergency Phone No.
 - : +82-33-243-1400

II. Hazard Identification		
GHS classification of the product and national or regional	le	
	Cartridge	
GHS classification	Not applicable	
IMDG Code	Not applicable	
GHS label elements including precautionary		
	Cartridge	
Symbols	No data available	
Signal word	No data available	
Hazard statements	No data available	
Precautionary statements	Cartridge	
Prevention	Cartridge No data available	
Reaction	No data available	
	No data available	
Storage Disposal	No data available No data available	
Other hazards		
Other Hazards	Cartridge	
	Housing	
	Health: 0	
NEPA	Flammability: 0	
Physical hazard: 0		

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III. Composition/Information on Ingredients

[Cartridge]

	Component	Synonyms	Classification No.	Amount (%)
Havein a	2-Methyl-2-propenoic acid methyl ester homopolymer	PMMA	9011-14-7	57~ 67
Housing	2-Propenenitrile polymer with 1,3- butadiene and ethenylbenzene	ABS	9003-56-9	33 ~ 43

IV. First Aid Measures

- In case of eye contact
- : Remove from source of exposure. Wash with copious amounts of water for at least 15 minutes. If irritation or signs of toxicity occur, seek medical attention.
- In case of skin contact
- : Remove from source of exposure. Wash affected area with soap and water. If irritation or signs of toxicity occur, seek medical attention.
- If inhaled
- : Get medical attention immediately. Remove to fresh air. If not breathe, give cardiopulmonary resuscitation. If breathing is difficult, give oxygen and continue to monitoring.
- If swallowed
- : If irritation or signs of toxicity occur, seek medical attention.
- * The following symptoms may occur: Irreversible eye damage.
- * Medical conditions aggravated by exposure: Pre-existing eye ailments. Hypersensitivity.
- * This material should be considered as being potentially infectious.

V. Fire Fighting Measures

- Recommended extinguishing media
- : Suitable extinguishing agents including $\mathrm{CO}_{2^{\prime}}$ WATER SPRAY or regular form.
- Specific hazard from the chemical
- : Non-flammable, Corrosive or toxic gases and fume may be occurred in fire-emergency. Inhalation may be harmful.
- Special measure for fire-fighters
 - : Rescuers need to note the personal protective equipment. If not danger, remove containers. Non-flammable, Corrosive or toxic gases and fume may be occurred in fire-emergency. Inhalation may be harmful.
- Protective Equipment and precautions for Fire fighters
- : Chemical resisted protective equipment for fire-fighter.

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VI. Accidential Release Measures

- Personal precautions
- * If not danger, stop to leak
- * Do not contact with exposed material without protective equipment
- * Note the avoid conditions and materials
- * Do not breathe dust / fume / gas / mist / vapours / spray
- Environmental precautions
- : No data available
- Methods and materials for purification and cleaning up
- : After absorbed exposed materials, clean up with cleaner and water.

VII. Handling and Storage

- Precaution for safe handling
- * Avoid skin friction.
- * Note the avoid conditions and materials from fire or flame.
- * Protective equipment: Chemical resisted protective goggles, gloves, clothes and mask
- Method for safe handling
- * Note the avoid conditions and materials.
- * Store container tightly closed in a well-ventilated area.
- * Storage temperature: low temperature

VIII. Exposure controls and Personal protection

- Engineering management
- : Good insolation and ventilation should be sufficient to control airborne levels.
- Personal protective equipment

Respiratory protection	Chemical resisted respiratory protection
Hand protection	Chemical resisted protective gloves
Eye protection	Chemical resisted eye protection
Skin and body protection	Chemical resisted protective clothes

- Standard of exposure

Chemical	No data available
Biological	No data available

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IX. Physical and Chemical properties

Cartridge			Diluent
	Test strip	Housing	
State	No data available	Natural color or pigment processed color	Liquid at 20℃
Odor	Odorless	Little odorless	No data available
Odor threshold value	No data available	No data available	No data available
рН	No data available	Natural	7.83
Melting/ Freezing point	No data available	180 ~ 200°C/ No data available	No data available
Initial boiling point or boiling range	No data available	No data available	No data available
Flash point	No flash occurred under 100°C (Closed-cup)	No data available	No flash occurred under 100°C (Closed-up)
Evaporating rate	No data available	No data available	No data available
Lower explosion limit	No data available	No data available	No data available
Upper explosion limit	No data available	No data available	No data available
Vapor pressure	No data available	No data available	No data available
Water solubility	No data available	Not soluble in water, soluble in acetone	No data available
Density	No data available	1.11	No data available
Vapor density	No data available	No data available	No data available
Specific gravity	No data available (water=1)	No data available (water=1)	1.01 (water=1)
N-octan/water partition coefficient	No data available	No data available	No data available
Auto-ignition temperature	No data available	No data available	No data available
Decomposition temperature	No data available	No data available	No data available
Viscosity	No data available	No data available	No data available
Molecular weight	No data available	50,000 ~ 250,000	No data available

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X. Stability and Reactivity

	Cartridge		Diluent Buffer
	Test strip	Housing	Diluent buller
Chaminal atability	- Irritation or toxic gases and fume may be occurred	- Stable at high	- Irritation or toxic gases and fume may be occurred
	in fire-emergency - Inhalation may harmful	temperature and pressure	in fire-emergency - Inhalation may harmful
Conditions to avoid	Heat, high temperature	Heat, high temperature above 200°C	Heat, high temperature
Materials to avoid	No data available	Oxidizing agent: fire or explosive risk	No data available
Hazardous decomposition products formed under fire conditions	Irritation or toxic gases and	fume may be occurred in fire-	emergency

XI. Toxicological Information

	Cartridge	Diluent buffer
Information on the likely routes of exposure	No data available	No data available
Acute toxicity	No data available	No data available
Skin corrosion/Irritation	No data available	No data available
Serious eye damage/Eye irritation	No data available	No data available
Respiratory/Skin sensitization	No data available	No data available
Germ cell mutagenicity	No data available	No data available
Carcinogenicity	No data available	No data available
Reproductive toxicity	No data available	No data available
Specific target organ toxicity(single exposure)	No data available	No data available
Specific target organ toxicity(repeated exposure)	No data available	No data available
Aspiration hazard	No data available	No data available

XII. Ecological Information

	Cartridge	Diluent buffer	
Toxicity	No data available	No data available	
Persistence and degradability	No data available	No data available	

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Bio-accumulative potential	No data available	No data available	
Mobility in soil	No data available	No data available	
Other adverse effects	No data available	No data available	

XIII. Disposal Consideration	ons	
	Test strip	Not available
Cartridge	Granule	Not available
	Housing	Consider the notice on Waste management act
Diluent buffer		Not available

XIV. Transport Information	
IMDG Code	No data available
DRF	No data available
RID	No data available
ADR	No data available
AND	No data available
IATA	Not regulated as dangerous good

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

XV. Regulatory Information

Korea Industrial Safety and Health Act	No data available
Korea Hazardous Materials Safety Control Act	No data available
Korea Toxic Chemical Control Act	No data available
Korea Wastes Control Act	No data available
Other internal and foreign acts	No data available

XVI. Other Notes

Limitations: The information and recommendations set forth in this MSDS are believed to be correct as of this date.

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