

SAFETY DATA SHEET

according to 29CFR1910.1200 (OSHA HCS) and Regulation (EC) No. 1907/2006

Date of Compilation/Revision Date: 2024-07-23
Revision Number: New
Replaces Revision: Not applicable

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name/Designation of the mixture: Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP)

Product code: K853M-20

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

Intended Use: For use as in vitro diagnostic quality control material.
Uses advised against: Not for use in/on humans or animals. Not for use in the manufacture of products to be used in/on humans or animals.

1.3 Details of the supplier of the safety data sheet

Supplier:
Aalto Scientific, Ltd.
230 Technology Parkway
Eatonton, GA 31024
USA
Customer service telephone: (760) 431-7922
Email (Competent Person): ehs@aaltoscientific.com
1.4 Emergency telephone number 1-800-748-6674

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

This product meets the criteria for classification in accordance with 29CFR1910.1200 (OSHA HCS) and Regulation (EC) No. 1272/2008 (CLP). This product is classified as a Skin Sensitizer Category 1.

In accordance with Regulation (EC) No. 1272/2008 (CLP), this product also meets the criteria for classification as Hazardous to the aquatic environment – Chronic, Category 3.

Once diluted, as it is intended to be used, this product does not meet the criteria for classification as a Skin Sensitizer Category 1

The most important adverse physicochemical, human health and environmental effects

2.2 Label elements

Hazard pictogram(s)



Signal word(s)

Warning

Hazard statement(s)

H317 May cause an allergic reaction

H412 Harmful to aquatic life with long lasting effects

Precautionary statement(s)

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment

P280 Wear protective gloves/protective clothing/eye protection

P302+P352 IF ON SKIN: Wash with plenty of water

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents in accordance with local, state, federal and international regulations.

2.3 Other hazards

Some components of this kit contain human and/or animal blood derivatives. No known test method can offer complete assurance that products derived from human and/or animal blood will not transmit infectious agents. Therefore, this material should be considered potentially infectious. Contains materials that could be toxic in large doses.

PBT criteria of REACH Annex XIII

Substance/mixture does not meet the PBT criteria of REACH regulation, Annex XIII

vPvB criteria of REACH Annex XIII

Substance/mixture does not meet the vPvB criteria of REACH regulation, Annex XIII

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier (CAS-No.) (EC No.)	Concentration (%w)	Classification of substance according to Regulation (EC) no. 1272/2008 and hazard statement(s)
N,N'-Dimethylthiourea	CAS No.: 534-13-4 EC No.: 208-588-2	0.08 – 0.98	Acute Tox. 3, H301 Skin Sens.1, H317
Sodium azide	CAS No.: 26628-22-8 EC No.: 247-852-1	0.09 -0.95	Acute Toxicity 2, H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Supplemental hazard statement: EUH032

Substances indicated in 3.2 (additional information)

Name	Specific concentration Limit/M- factor(s)	Acute Toxicity Estimate	Reason for indicating the substance
N,N'-Dimethylthiourea	—	No data available	Not applicable.
Sodium azide	—	27 mg/kg (oral) 20 mg/kg (dermal) 0.054 – 0.52 mg/l/4h - dust/mist (inhalation)	Not applicable.

For full hazard and supplemental hazard statements refer to Section 16 of this SDS.

SECTION 4: First aid measures

4.1 Description of first aid measures

First-aid measures general

Seek medical advice/attention if you feel unwell.

In case of eye contact:

May Cause irritation. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Continue rinsing eyes during transport to hospital.

In case of skin contact:

Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician

In case of ingestion:

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

In case of inhalation:

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Protection of first-aid providers

4.2 Most important symptoms and effects, both acute and delayed

4.3 Indication of any immediate medical attention and special treatment needed

Wear suitable gloves and eye/face protection.

The most important known symptoms and effects are described in the labeling (see Section 2.2) and/or Section 11 of this SDS.

No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Extinguishing media which must not be used for safety reasons

None to our knowledge.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:

None to our knowledge.

Combustion products or resulting gases:

None to our knowledge.

5.2 Special hazards arising from the substance or mixture

None to our knowledge.

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective suit.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For emergency responders and non-emergency personnel

Wear suitable gloves and eye/face protection. Handle all blood and materials in contact with blood as if capable of transmitting infectious agents. It is recommended that blood and materials in contact with blood be handled using established good laboratory practices.

6.2 Environmental precautions

Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.

6.3 Methods and material for containment and cleaning up

Containment techniques

Use appropriate adsorbent material.

Spill clean-up

Use appropriate adsorbent material.

6.4 Reference to other sections

See Sections 8 and 13 for Exposure controls/personal protection and waste handling.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations for safe handling

Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Wear appropriate personal protective equipment - see Section 8.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Keep away from sources of ignition. Keep separate from acidic/basic solutions.

7.3 Specific end use(s)

For professional use only.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 Individual protection measures

Eye/face protection

Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Hand protection

Wear suitable gloves resistant to chemical penetration. Nitrile rubber gloves. Layer thickness : 0.11mm. Breakthrough time : 60 min.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multipurpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Body protection

Wear clothing suitable for a laboratory environment including (but not limited to) a lab coat and closed toed shoes.

Ingredients with workplace control parameters (US)

Component	CAS-No.	Value	Control parameters	Basis
Sodium azide	26628-22-8	C	0.29 mg/m3	USA. ACGIH Threshold Limit Values (TLV)

	Remarks	Not classifiable as a human carcinogen		
		C	0.11 ppm	USA. ACGIH Threshold Limit Values (TLV)
		Not classifiable as a human carcinogen		
			0.1 ppm	USA. NIOSH Recommended Exposure Limits
		Potential for dermal absorption		
		C	0.3 mg/m3	USA. NIOSH Recommended Exposure Limits
		Potential for dermal absorption		
		C	0.1 ppm	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
		Skin notation		
		C	0.3 mg/m3	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
		Skin notation		
		C	0.1 ppm 0.3 mg/m3	California permissible exposure limits for chemical contaminants (Title 8, Article 107)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	Solid.	Decomposition temperature:	No information available.
Colour:	No information available.	pH:	No information available.
Odour:	No information available.	Kinematic viscosity:	No information available.
Melting point/freezing point:	No information available.	Solubility:	No information available.
Boiling point:	No information available.	Partition coefficient n-octanol/water (log value):	No information available.
Flammability:	No information available.	Vapour pressure:	No information available.
Lower and upper explosion limit:	No information available.	Density/relative density:	No information available.
Flash point:	No information available.	Relative vapour density:	No information available.
Autoignition temperature:	No information available.	Particle characteristics:	No information available.

9.2 Other Information

No other information available.

SECTION 10: Stability and reactivity

10.1 Reactivity	Stable under normal conditions.
10.2 Chemical stability	Stable under normal conditions.
10.3 Possibility of hazardous reactions	No information available.
10.4 Conditions to avoid	Temperatures outside of the specified storage range.
10.5 Incompatible materials	Acids, Peroxides, Acid chlorides, Metals, Oxidizing agents.
10.6 Hazardous decomposition products	Thermal decomposition can lead to release of irritating gases and vapors. Metals and metallic compounds: Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

SECTION 11: Toxicological information

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

Acute toxicity:	Not classified. Based on available data, classification criteria are not met.
Skin corrosion/irritation:	Not classified. Based on available data, classification criteria are not met.
Serious eye damage/irritation:	Not classified. Based on available data, classification criteria are not met.
Respiratory or skin sensitization:	

N,N'-Dimethylthiourea

No data available.

Germ cell mutagenicity:	Not classified. Based on available data, classification criteria are not met.
Carcinogenicity:	Not classified. Based on available data, classification criteria are not met.
Reproductive toxicity:	Not classified. Based on available data, classification criteria are not met.
STOT-single exposure:	Not classified. Based on available data, classification criteria are not met.
STOT-repeated exposure:	Not classified. Based on available data, classification criteria are not met.
Aspiration hazard:	Not classified. Based on available data, classification criteria are not met.
11.2 Information on other hazards	Not established as having endocrine disrupting properties.

SECTION 12: Ecological information

12.1 Toxicity

Sodium azide (CAS No. 26628-22-8)	
Toxicity to fish (acute)	flow-through test LC50 - Oncorhynchus mykiss (rainbow trout) - 2.75 mg/L - 96 h (OECD Test Guideline 203)
Toxicity to algae (acute)	static test ErC50 - Pseudokirchneriella subcapitata - 0.35 mg/L - 96 h (OECD Test Guideline 201)

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

Substance/mixture does not meet the PBT or vPvB criteria of REACH regulation, Annex XIII

12.6 Endocrine disrupting properties

Not established as having endocrine disrupting properties.

12.7 Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/container in accordance with licensed collector's sorting instructions. Sewage disposal is discouraged. Handle product as if it is capable of transmitting infectious disease.

SECTION 14: Transport information

ADR	IMDG	IATA	ADN	RID
14.1 UN number/ID number				
Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
14.2 UN proper shipping name				
Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
14.3 Transport hazard class				
Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
14.4 Packing group				
Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.

14.5 Environmental hazards

Not regulated for transportation

14.6 Special precautions for user:

None.

14.7 Maritime transport in bulk according to IMO instruments:

Not applicable.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Restrictions according to REACH, Annex XVII: Not listed

15.2 Chemical safety assessment No chemical safety assessment has been carried out.

U.S. Federal Regulations:	
U.S. CERCLA/SARA/TSCA Regulatory Information:	This Product does not contain any chemicals currently listed on the Section 302/312, SARA Title III above the OSHA de minimis concentration. This product does not contain any chemicals currently listed with a CERCLA RQ above the OSHA de minimis concentration.
California Proposition 65	This product contains trace amounts of the following substances known to the State of California to cause Cancer and/or reproductive harm: None.

SECTION 16: Other information

This data sheet contains changes from the previous version in section(s):
Not applicable.

Restrictions on use:

This product is not for human consumption. This product is not for use in/on humans or animals.

Additional advice:

None.

Full text of H- and EUH- statements not written out in full under Sections 2 to 15:

H300	Fatal if swallowed
H301	Toxic if swallowed.
H317	May cause an allergic skin reaction
H373	May cause damage to organs (Brain) through prolonged or repeated exposure if swallowed.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
EUH032	Contact with acids liberates very toxic gas

Data Sources: Component manufacturer, 1907/2006/EC (REACH), 1272/2008/EC (CLP)

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End of Safety Data Sheet