

Revision date 10-Sep-2024

Revision Number 1

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

### 1.1. Product identifier

**Product Code(s)** 8505

**Product Name** HAV Grade II Concentrate

### Other means of identification

**Pure substance/mixture** Mixture

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

**Recommended use** In vitro diagnostic

**Uses advised against** No information available

### 1.3. Details of the supplier of the safety data sheet

#### **Manufacturer**

Meridian Bioscience, Inc. 5171 Wilfong Road, Memphis, TN 38134  
For further information, please contact:

**E-mail Address** info@meridianlifescience.com

### 1.4. Emergency telephone number

**Emergency Telephone** Emergency telephone CHEMTREC:  
US: 1-800-424-9300  
International: 1-703-527-3887  
Philippines: 1800 1 322 0553  
Taiwan: 00801-49-1821  
Thailand: 1800014808  
South Korea: 080-880-0454  
Asia-Pacific: +65 3163 8374

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Classification according to

Regulation (EC) No. 1272/2008 [CLP]

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

### 2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

### **Hazard statements**

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

EUH208 - Contains Formaldehyde May produce an allergic reaction.

### **Precautionary Statements - EU (§28, 1272/2008)**

The chemical, physical and toxicological properties of this mixture have not been thoroughly characterized. Avoid contact with eyes and skin. Do not inhale. This material was originally sourced from Hepatitis A virus infected fetal rhesus kidney cells (FRhK4) cultured in presence of fetal bovine serum. All animal sourced materials were sourced and qualified from United States to be free from BSE/TSE which were used in the manufacture of this product. This material should be considered as potentially capable of transmitting infectious disease..

### **Unknown aquatic toxicity**

Contains 98.8274 % of components with unknown hazards to the aquatic environment.

### 2.3. Other hazards

No information available.

### **Endocrine Disruptor Information**

This product does not contain any known or suspected endocrine disruptors.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable

### 3.2 Mixtures

The product contains no substances which at their given concentration, are considered to be hazardous to health

### **Full text of H- and EUH-phrases: see section 16**

### Acute Toxicity Estimate

No information available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
<b>Ingestion</b>	Rinse mouth.

### 4.2. Most important symptoms and effects, both acute and delayed

<b>Symptoms</b>	No information available.
<b>Effects of Exposure</b>	No information available.

### 4.3. Indication of any immediate medical attention and special treatment needed

<b>Note to physicians</b>	Treat symptomatically.
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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.

### 5.2. Special hazards arising from the substance or mixture

<b>Specific hazards arising from the chemical</b>	No information available.
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### 5.3. Advice for firefighters

<b>Special protective equipment and precautions for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

<b>Personal precautions</b>	Ensure adequate ventilation.
<b>For emergency responders</b>	Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

<b>Environmental precautions</b>	See Section 12 for additional Ecological Information.
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### 6.3. Methods and material for containment and cleaning up

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Take up mechanically, placing in appropriate containers for disposal.
<b>Prevention of secondary hazards</b>	Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

<b>Reference to other sections</b>	See section 8 for more information. See section 13 for more information.
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## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

<b>Advice on safe handling</b>	Ensure adequate ventilation.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

<b>Storage Conditions</b>	Keep container tightly closed in a dry and well-ventilated place.
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### 7.3. Specific end use(s)

<b>Identified uses</b>	
<b>Risk Management Methods (RMM)</b>	The information required is contained in this Material Safety Data Sheet.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters**

**Exposure Limits** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

**Biological occupational exposure limits** This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

**Derived No Effect Level (DNEL) - Workers** No information available

**Derived No Effect Level (DNEL) - General Public** No information available.

**Predicted No Effect Concentration (PNEC)** No information available.

**8.2. Exposure controls**

**Engineering controls** No information available.

**Personal protective equipment**

**Eye/face protection** No special protective equipment required.

**Skin and body protection** No special protective equipment required.

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

**Environmental exposure controls** No information available.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Liquid
Color	Clear to Light Yellow
Odor	No information available.
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	Open cup
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	8.2 ± 0.2	@ 20 °C
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Miscible with water	20 °C in g/L
Solubility(ies)	no data available	in fatty substances :
Partition coefficient	No data available	None known
Vapor pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapor density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

### 9.2. Other information

9.2.1. Information with regard to physical hazard classes  
Not applicable

9.2.2. Other safety characteristics  
No information available

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**SECTION 10: Stability and reactivity****10.1. Reactivity**

**Reactivity** No information available.

**10.2. Chemical stability**

**Stability** Stable under normal conditions.

**Explosion data**

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

**10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** None under normal processing.

**10.4. Conditions to avoid**

**Conditions to avoid** None known based on information supplied.

**10.5. Incompatible materials**

**Incompatible materials** None known based on information supplied.

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** None known based on information supplied.

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Information on likely routes of exposure****Product Information**

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available.

**Symptoms related to the physical, chemical and toxicological characteristics**

**Symptoms** No information available.

**Acute toxicity****Numerical measures of toxicity**

The following values are calculated based on chapter 3.1 of the GHS document

<b>ATEmix (oral)</b>	99,999.00 mg/kg
<b>ATEmix (dermal)</b>	99,999.00 mg/kg
<b>ATEmix (inhalation-gas)</b>	99,999.00 ppm
<b>ATEmix (inhalation-vapor)</b>	99,999.00 mg/l
<b>ATEmix (inhalation-dust/mist)</b>	99,999.00 mg/l

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Skin corrosion/irritation** No information available.

**Serious eye damage/eye irritation** No information available.

**Respiratory or skin sensitization** No information available.

**Germ cell mutagenicity** No information available.

**Carcinogenicity** No information available.

**Reproductive toxicity** No information available.

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Aspiration hazard** No information available.

### **11.2. Information on other hazards**

#### **11.2.1. Endocrine disrupting properties**

**Endocrine disrupting properties** No information available.

#### **11.2.2. Other information**

**Other adverse effects** No information available.

## **SECTION 12: Ecological information**

### **12.1. Toxicity**

#### **Ecotoxicity**

**Unknown aquatic toxicity** Contains 98.8274 % of components with unknown hazards to the aquatic environment.

### **12.2. Persistence and degradability**

**Persistence and degradability** No information available.

### **12.3. Bioaccumulative potential**

**Bioaccumulation** There is no data for this product.

### **12.4. Mobility in soil**

**Mobility in soil** No information available.

### **12.5. Results of PBT and vPvB assessment**

**PBT and vPvB assessment** The product does not contain any substance(s) classified as PBT or vPvB above the threshold of declaration.

### **12.6. Endocrine disrupting properties**

**Endocrine disrupting properties** No information available.

## **Product Information**

### **12.7. Other adverse effects**

No information available.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

**SECTION 14: Transport information****IATA**

<b>14.1. UN number or ID number</b>	Not regulated
<b>14.2. UN proper shipping name</b>	Not regulated
<b>14.3. Transport hazard class(es)</b>	Not regulated
<b>14.4. Packing group</b>	Not regulated
<b>14.5. Environmental hazards</b>	No
<b>14.6. Special precautions for user</b>	
<b>Special Provisions</b>	None

**IMDG**

<b>14.1. UN number or ID number</b>	Not regulated
<b>14.2. UN proper shipping name</b>	Not regulated
<b>14.3. Transport hazard class(es)</b>	Not regulated
<b>14.4. Packing group</b>	Not regulated
<b>14.5. Environmental hazards</b>	No
<b>14.6. Special precautions for user</b>	
<b>Special Provisions</b>	None
<b>14.7. Maritime transport in bulk according to IMO instruments</b>	No information available

**RID**

<b>14.1. UN number or ID number</b>	Not regulated
<b>14.2. UN proper shipping name</b>	Not regulated
<b>14.3. Transport hazard class(es)</b>	Not regulated
<b>14.4. Packing group</b>	Not regulated
<b>14.5. Environmental hazards</b>	No
<b>14.6. Special precautions for user</b>	
<b>Special Provisions</b>	None

**ADR**

<b>14.1. UN number or ID number</b>	Not regulated
<b>14.2. UN proper shipping name</b>	Not regulated
<b>14.3. Transport hazard class(es)</b>	Not regulated
<b>14.4. Packing group</b>	Not regulated
<b>14.5. Environmental hazards</b>	No
<b>14.6. Special precautions for user</b>	
<b>Special Provisions</b>	None

## SECTION 15: Regulatory information

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

#### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### Persistent Organic Pollutants

Not applicable

#### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

#### International Inventories

<b>TSCA</b>	Contact supplier for inventory compliance status
<b>DSL/NDSL</b>	Contact supplier for inventory compliance status
<b>EINECS/ELINCS</b>	Contact supplier for inventory compliance status
<b>ENCS</b>	Contact supplier for inventory compliance status
<b>IECSC</b>	Contact supplier for inventory compliance status
<b>KECL</b>	Contact supplier for inventory compliance status
<b>PICCS</b>	Contact supplier for inventory compliance status
<b>AIC</b>	Contact supplier for inventory compliance status
<b>NZIoC</b>	Contact supplier for inventory compliance status

#### Legend:

- TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
- DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
- EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
- ENCS** - Japan Existing and New Chemical Substances
- IECSC** - China Inventory of Existing Chemical Substances
- KECL** - Korean Existing and Evaluated Chemical Substances
- PICCS** - Philippines Inventory of Chemicals and Chemical Substances
- AICS** - Australian Inventory of Chemical Substances
- NZIoC** - New Zealand Inventory of Chemicals

### 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

**SECTION 16: Other information****Key or legend to abbreviations and acronyms used in the safety data sheet****Legend**

SVHC: Substances of Very High Concern for Authorization:

PBT: Persistent, Bioaccumulative, and Toxic (PBT) Substances

vPvB: Very Persistent and very Bioaccumulative (vPvB) Substances

**Legend Section 8: Exposure controls/personal protection**

TWA Time weighted average

STEL

Short term exposure limit

Ceiling Maximum limit value:

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Skin designation

+ Sensitizers

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA\_RAC)

European Chemicals Agency (ECHA) (ECHA\_API)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

National Institute of Technology and Evaluation (NITE)

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

Revision date 10-Sep-2024

**Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)**

**Disclaimer**

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**

**Europe**

**EU SDS version information - EGHS**

UL release:

GHS Revision 7

2023 Q1

**Europe**

Partial process, including GHS Wizard, NO TW