

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**

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

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

Symptoms	No information available.
Effects of Exposure	No information available.

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

Note to physicians	Treat symptomatically.
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SECTION 5: Firefighting measures**5.1. Extinguishing media**

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

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	No information available.
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5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	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

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

6.2. Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.
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6.3. Methods and material for containment and cleaning up

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

6.4. Reference to other sections

Reference to other sections	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

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

7.2. Conditions for safe storage, including any incompatibilities

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

Identified uses	
Risk Management Methods (RMM)	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

Property	Values	Remarks • Method
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

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**

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

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	No information available.
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Acute toxicity**Numerical measures of toxicity**

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

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

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information**IATA**

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

IMDG

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

RID

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

ADR

14.1. UN number or ID number Not regulated
14.2. UN proper shipping name Not regulated
14.3. Transport hazard class(es) Not regulated
14.4. Packing group Not regulated
14.5. Environmental hazards No
14.6. Special precautions for user
Special Provisions 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

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status
NZIoC	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
AIIC - 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