

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

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

1.1 Product identifier

Product Name: Ferritin Controls

Product code: F7505-CTL

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

Relevant identified uses: The Pointe Ferritin Control Set is intended for use as a consistent test sample of known concentration for monitoring the performance of the Pointe Ferritin immunoturbidimetric assay with serum or plasma samples. For in vitro use only. Rx Only.

Uses advised against: Not determined or not applicable.

Reasons why uses advised against: Not determined or not applicable.

1.3 Details of the manufacturer/supplier of the safety data sheet

Manufacturer:

United States

HORIBA Instruments Incorporated

5449 Research Drive

Canton, MI 48188

734-487-8300

horiba.com

1.4 Emergency telephone number:

United States

HORIBA Instruments Incorporated

1-800-445-9853 (24 hours per day)

France

Organisme de conseil/centre antipoison national

+33 1 45 42 59 59 (24 hours per day)

Portugal

Órgão consultor nacional/Centro Antivenenos

+351 800 250 250 (24 hours per day)

Spain

Centro de información toxicológica/organismo asesor nacional

+34 91 562 04 20 (24 hours per day)

Czech Republic

Národní poradní orgán/toxikologické středisko

+420 224 919 293 (24 hours per day)

Greece

Εθνικό συμβουλευτικό όργανο/Κέντρο Δηλητηριάσεων

+30 210 779 3777 (24 hours per day)

Italy

Organismo ufficiale di consultazione nazionale/Centro antiveleni

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+39 06 305 4343 (24 hours per day)

Romania

Organism consultativ național/Centru pentru otrăviri
+40 21 3183606 (24 hours per day)

Poland

Krajowa instytucja doradcza/Ośrodek zatruc
+48 22 619 66 54 (24 hours per day)

SECTION 2: Hazard(s) identification

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No. 1272/2008 (CLP): The substance is not classified as hazardous according to the Globally Harmonized System (GHS).

Hazard-determining components of labeling: None

Additional Information:

This product contains human serum ingredients. It has been prepared from human sera that tested negative for HBsAg and HIV antibodies by FDA-approved methods. In view of the fact that no test method can completely assure the absence of hepatitis B virus (HBV), human immunodeficiency virus (HIV), or other infectious agents, the product should be treated like patient specimens that are potentially infectious and handled with appropriate caution.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Hazard pictograms: None

Signal Word: None

Hazard statements: None

Precautionary statements: None

2.3 Other hazards: None known

SECTION 3: Composition/information on ingredients

3.1 Substance: Not applicable.

3.2 Mixture: There are no components present in the mixture which are classified as hazardous.

Additional information: None

Full Text of H and EUH statements: See section 16

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes:

Show this Safety Data Sheet to the doctor in attendance.

Following inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. If respiratory symptoms develop or persist, seek medical advice/attention.

Following skin contact:

Wash affected area with plenty of soap and water. Remove contaminated clothing and launder before reuse. If skin irritation develops or persists, seek medical advice/attention.

Following eye contact:

Immediately rinse eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for

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and remove any contact lenses. Continue to rinse for at least 15 minutes. If eye irritation develops or persists, seek medical advice/attention.

Following ingestion:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Self-Protection of the first aider:

Not determined or not available.

4.2 Most important symptoms and effects, both acute and delayed

Acute symptoms and effects: Not determined or not available.

Delayed symptoms and effects:

Not determined or not available.

4.3 Indication of any immediate medical attention and special treatment needed

Specific treatment:

Not determined or not available.

Notes for the doctor:

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Water mist/fog, carbon dioxide, dry chemical or alcohol resistant foam.

Unsuitable extinguishing media:

Do not use water jet.

5.2 Special hazards arising from the substance or mixture:

Thermal decomposition may produce irritating/toxic fumes/gases.

5.3 Advice for firefighters

Personal protection equipment:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA).

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts. Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

6.2 Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain and collect spillage and place in suitable

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container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

6.4 Reference to other sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

7.2 Conditions for safe storage, including any incompatibilities:

Keep frozen before use for maximum shelf life. After thawing for use, store between +2°C and +8°C, tightly closed. Do not re-freeze after thaw.

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10).

7.3 Specific end use(s):

Refer to Section 1 (Recommended Use).

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Only those substances with limit values have been included below.

Occupational Exposure limit values:

No occupational exposure limits noted for the ingredient(s).

Biological limit values:

No biological exposure limits noted for the ingredient(s).

Derived No Effect Level (DNEL):

Not determined or not applicable.

Predicted No Effect Concentration (PNEC):

Not determined or not applicable.

Information on monitoring procedures:

Not determined or not applicable.

8.2 Exposure controls

Appropriate engineering controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal protection equipment

Eye and face protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and body protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a

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specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General hygienic measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

Environmental exposure controls:

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Product (substance / mixture) related measures to prevent exposure:	Not determined or not applicable.
Instruction measures to prevent exposure:	Not determined or not applicable.
Organisational measures to prevent exposure:	Not determined or not applicable.
Technical measures to prevent exposure:	Not determined or not applicable.

Risk management measures to control exposure:

Not determined or not applicable.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical State	Provided in liquid form.
Color	Light yellow to amber solution.
Odor/Odor threshold	Not determined or not available.
pH	Not determined or not available.
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.
Flammability	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapor pressure	Not determined or not available.
Relative vapor density	Not determined or not available.
Density	Not determined or not available.
Relative density	Not determined or not available.
Solubilities	Miscible in Water
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Particle characteristics	Not determined or not available.

9.2 Other information

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9.2.1 Information with regard to physical hazard classes

Explosives	No data available/Not applicable
Flammable gases	No data available/Not applicable
Aerosols	No data available/Not applicable
Oxidizing gases	No data available/Not applicable
Gases under pressure	No data available/Not applicable
Flammable liquids	No data available/Not applicable
Flammable solids	No data available/Not applicable
Self-reactive substances and mixtures	No data available/Not applicable
Pyrophoric liquids	No data available/Not applicable
Pyrophoric solids	No data available/Not applicable
Self-heating substances and mixtures	No data available/Not applicable
Substances and mixtures, which emit flammable gases in contact with water	No data available/Not applicable
Oxidizing liquids	No data available/Not applicable
Oxidizing solids	No data available/Not applicable
Organic peroxides	No data available/Not applicable
Corrosive to metals	No data available/Not applicable
Desensitized explosives	No data available/Not applicable

9.2.2 Other safety characteristics

None.

SECTION 10: Stability and reactivity

10.1 Reactivity:

Not reactive under recommended handling and storage conditions.

10.2 Chemical stability:

Stable under recommended handling and storage conditions.

10.3 Possibility of hazardous reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

10.4 Conditions to avoid:

Extreme heat, open flames, hot surfaces, sparks, ignition sources and incompatible materials.

10.5 Incompatible materials:

Caution, contains Sodium Azides, in contact with heavy metals, may form explosive metal azides.

10.6 Hazardous decomposition products:

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

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Skin corrosion/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Serious eye damage/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Respiratory or skin sensitization

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

Germ cell mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Reproductive Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Specific target organ toxicity (single exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Specific target organ toxicity (repeated exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Information on likely routes of exposure:

No data available.

Symptoms related to the physical, chemical and toxicological characteristics:

No data available.

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11.2 Information on other hazards

Endocrine disrupting properties:

Substance data: No data available.

Other information:

No data available.

SECTION 12: Ecological information

12.1 Toxicity

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Chronic (long-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

12.2 Persistence and degradability

Product data: No data available.

Substance data: No data available.

12.3 Bioaccumulative potential

Product data: No data available.

Substance data: No data available.

12.4 Mobility in soil

Product data: No data available.

Substance data: No data available.

12.5 Results of PBT and vPvB assessment

Product data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Substance data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

12.6 Endocrine disrupting properties

Substance data: No data available.

12.7 Other adverse effects: No data available.

12.8 Hazard to the ozone layer

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

13.1.1 Product / Packaging disposal:

The product has to be disposed of in accordance with local regulations. Do not wash away into surface water or sanitary sewer systems.

Waste codes / waste designations according to LoW: Not determined or not available.

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13.1.2 Waste treatment-relevant information: Not determined or not available.

13.1.3 Sewage disposal-relevant information: Not determined or not available.

13.1.4 Other disposal recommendations: It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities

SECTION 14: Transport information

International Carriage of Dangerous Goods by Road/Rail (ADR/RID)

UN number or ID number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Carriage of Dangerous Goods by Inland Waterways (ADN)

UN number or ID number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Maritime Dangerous Goods (IMDG)

UN number or ID number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Air Transport Association Dangerous Goods Regulations (IATA-DGR)

UN number or ID number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

Maritime Transport in Bulk according to IMO Instruments

Bulk Name	None
Ship type	None
Pollution category	None
IMO hazard class	None

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Environmental hazards	None
Material hazardous only in bulk	None
Cargo Group	None

SECTION 15: Regulatory information

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

European regulations

Inventory listing (EINECS): Not determined.

REACH SVHC candidate list: Not determined.

REACH SVHC Authorizations: Not determined.

REACH Restriction: Not determined.

Water hazard class (WGK) (Product): Not determined.

Water hazard class (WGK) (Substance): Not determined.

Other regulations

Germany TA Luft: Not determined.

Additional information: Not determined.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: Other information

Abbreviations and Acronyms: None

Disclaimer:

This product has been classified in accordance with EC No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and EC No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation, and disposal 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, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

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End of Safety Data Sheet