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SAFETY DATA SHEET

HELENA LABORATORIES 1530 Lindbergh Dr. Beaumont, TX 77707 USA Toll Free 800-231-5663

DATE PREPARED: 2/2/2024

REVISION: 5

1. IDENTIFICATION

Product number: 3457

Product identifier used on the label: SPIFE IFE-9 Pentavalent Kit

Other means of identification:

Component Name	Component Number
552563, SPIFE IFE-9 Gel Kit	
SPIFE IFE-9 Gel	552537
Acid Violet Stain	551758
Citric Acid Destain	551959
Tris Buffered Saline	551715
552229, SPIFE IFE-9 Pentavalent Antisera Kit	
SPIFE IFE-9 Pentavalent Fixative	552232
SPIFE IFE-9 Pentavalent Antisera	552234

Recommended use of the chemical and restrictions in use: For In-Vitro Diagnostic use.

Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party:

Helena Laboratories 1530 Lindbergh Dr. Beaumont, TX 77707

Tel: (409) 842-3714

USE Toll Free 800-231-5663

Emergency phone number:

(409) 842-3714

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2. HAZARD IDENTIFICATION

Classification of the chemical:

Component Name	GHS Classification	Hazard Statement
552563, SPIFE IFE-9 Gel Kit		
SPIFE IFE-9 Gel	Not Classified	Harmful if swallowed
Citric Acid Destain (Powder)	Eye/Skin (Category 2)	Irritant
Tris Buffered Saline	Eye/Skin (Category 2))	Irritant
552229, SPIFE IFE-9 Pentavalent Antisera Kit		
SPIFE IFE-9 Pentavalent Fixative	Eye/Skin (Category 2)	Corrosive

NOTE: All other components present no significant physical or chemical hazard.

NOTE: Citric Acid Destain Solution is not hazardous (< 1%) when dissolved following instructions on label.

Label elements:

SPIFE IFE-9 Gel Kit: Signal word: Warning

SPIFE IFE-9 Pentavalent Antisera Kit: Signal word: Danger

Precautionary statements:

Skin: May cause skin irritation

Eye: May cause eye irritation

Inhalation: May be harmful if inhaled

Ingestion: May be harmful if swallowed

Wear protective gloves/protective clothing/eye and face protection.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component Name	Chemical Name	CAS#	Concentration
SPIFE IFE-9 Gel	Sodium Barbital	144-02-5	1.3%
Citric Acid Destain	Citric Acid	77-92-9	100%
Tris Buffered Saline	Trizma Base	77-86-1	40%
SPIFE IFE-9 Pentavalent Fixative	5-Sulfosalicylic Acid	5965-83-3	4%
	Trichloroacetic Acid	76-03-9	6.7%
	Guanidine Hydrochloride	50-01-1	1.7%

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4. FIRST AID MEASURES

Description of first aid measures:

Inhalation: Remove person to fresh air. If not breathing, give artificial respiration. Consult a

physician.

Skin contact: Immediately wash off with soap and plenty of water. If skin irritation occurs, get

medical attention. Take off contaminated clothing.

Eye contact: Immediately flush eyes with plenty of water for at least 15 minutes. Consult a

physician.

Ingestion: Do not induce vomiting. Rinse mouth with water. Consult a physician.

5. FIREFIGHTING MEASURES

Extinguishing media: Water spray, dry chemical, carbon dioxide, or alcohol resistant foam.

Special hazards arising from the substance or mixture: Carbon dioxides, sulfur.

Special protective equipment and precautions for firefighters: Wear proper protective equipment and self contained breathing apparatus for firefighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear personal protective equipment. Evacuate personnel to safe areas. Soak up with inert absorbent material and transfer to container for proper disposal.

Methods and materials for containment and cleaning up: Do not allow material to enter drains/surface water/ground water. Ventilate the area.

7. HANDLING AND STORAGE

Precautions for safe handling: Wear personal protective equipment; avoid contact with skin and eyes.

Conditions for safe storage, including any incompatibilities: Store all kit components as per specified instructions.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits (AGGIH TLV & OSHA PEL):

Chemical Name	AGGIH TLV	OSHA PEL
Sodium Barbital	None listed	None listed
Citric Acid	None listed	None listed
Trizma Base	None listed	None listed
5-Sulfosalicylic Acid	None listed	None listed
Trichloroacetic Acid	1 ppm	None listed
Guanidine Hydrochloride	None listed	None listed

Exposure controls:

Respiratory protection: Use NOISH approved respirators if necessary.

Skin protection: Wear appropriate protective gloves and suitable protective clothing.

Eye protection: Wear appropriate safety glasses or goggles.

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

SPIFE IFE-9 Gel

Appearance: Solid (gel)

Odor: None

Odor threshold: No data available

pH: Not applicable

Melting point/Freezing point: No data available

Initial boiling point and range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): No data available

Upper/lower flammability or explosive limits: No data available

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Vapor pressure: No data available

Relative density: No data available

Solubility in water: Soluble

Partition coefficient: n-octanol/water: No data available

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity: No data available

Citric Acid Destain (Powder)

Appearance: White crystalline

Odor: None

Odor threshold: No data available

pH: 1.8 at 50 g/L

Melting point/Freezing point: 153-159°C

Initial boiling point and range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): No data available

Upper/lower flammability or explosive limits: No data available

Vapor pressure: No data available

Relative density: No data available

Solubility in water: Soluble

Partition coefficient: n-octanol/water: No data available

Auto-ignition temperature: No data available

Decomposition temperature: No data available

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Viscosity: No data available

Tris Buffered Saline

Appearance: White crystalline powder

Odor: None

Odor threshold: No data available

pH: 8.2-8.8 (when dissolved following instructions on label)

Melting point/Freezing point: No data available

Initial boiling point and range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): No data available

Upper/lower flammability or explosive limits: No data available

Vapor pressure: No data available

Relative density: No data available

Solubility in water: Soluble

Partition coefficient: n-octanol/water: No data available

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity: No data available

SPIFE IFE-9 Pentavalent Fixative

Appearance: Liquid

Odor: None

Odor threshold: No data available

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pH: < 2

Melting point/Freezing point: No data available

Initial boiling point and range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): No data available

Upper/lower flammability or explosive limits: No data available

Vapor pressure: No data available

Relative density: No data available

Solubility in water: Soluble

Partition coefficient: n-octanol/water: No data available

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity: No data available

10. STABILITY AND REACTIVITY

Reactivity: Not normally reactive

Chemical stability: Stable under normal condition

Possibility of hazard reaction: Hazardous polymerization does not occur

Conditions to avoid: Avoid contact with incompatible materials and heat.

Incompatible materials: Oxidizing agents, strong bases

Hazard decomposition products: Hazard decomposition products formed under fire conditions:

Carbon oxides

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11. TOXICOLOGICAL INFORMATION

The calculated ATE value:

SPIFE IFE-9 Gel LD50 oral = 50000 mg/kg

Citric Acid Destain (Powder) LD50 oral = 5040 mg/kg

NOTE: Citric Acid Destain is not hazardous (< 1%) when dissolved following instructions on label.

Tris Buffered Saline LD50 oral = 7692 mg/kg

SPIFE IFE-9 Pentavalent Fixative LD50 oral = 16667 mg/kg

See the following table for individual ingredient acute toxicity data:

Chemical Name	LD 50 (oral, rat)
Sodium Barbital	600 mg/kg
Citric Acid	5040 mg/kg
Trizma Base	>3000 mg/kg
5-Sulfosalicylic Acid	2450 mg/kg
Trichloroacetic Acid	3320 mg/kg
Guanidine Hydrochloride	475 mg/kg

Potential health effects:

Inhalation: May be harmful if inhaled

Ingestion: May be harmful if swallowed

Skin: May cause skin irritation

Eye: May cause eye irritation

Carcinogenicity: No components are listed as carcinogens by AGGIH, IARC, OSHA or NTP.

Other important toxicological hazards: To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

Eco-toxicity: No data available

Persistence and degradability: No data available

Bio-accumulative potential: No data available

Mobility in soil: No data available

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Other adverse effects: No data available
13. DISPOSAL CONSIDERATION
Observe all federal, state and local regulations.
14. TRANSPORT INFORMATION
DOT (US):
SPIFE IFE-9 Gel Kit - Not regulated
SPIFE IFE-9 Pentavalent Antisera Kit- Regulated as Hazardous Material during transportation.
UN number:
UN proper shipping name:
Transport hazard class:
Packing group:
15. REGULATORY INFORMATION
US State Right to Know Laws:
California Proposition 65: This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.
Other US State "Right to Know" List: The following chemicals are listed by individual States:
Citric Acid (PA, NJ)
Trizma Base (PA, NJ)
Guanidine Hydrochloride (PA, NJ)

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16. OTHER INFORMATION

SDS Creation date: 5/7/2014

Revision #: 5

Disclaimer

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Helena Laboratories shall not be held liable for any damage resulting from handling or from contact with the above product.