

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: ELVIS HSV ID and D³ Test System (Catalog #: SKT-ELVIS-60.v2)

Intended Use: A test system for the culture, identification and typing of *Herpes simplex virus* (HSV), using the *Enzyme Linked Virus Inducible System (ELVIS)*. This kit is for *in vitro* diagnostic use.



Components: ELVIS HSV Solution 1 (Cell Fixative), ELVIS HSV Solution 2T (Staining Buffer), ELVIS HSV Solution 3, ELVIS HSV Mounting Fluid (Buffered Glycerol), and 40X PBS Concentrate; ELVIS HSV Cells and ELVIS HSV Replacement Medium purchased separately.

Section 2 – Hazards Identification




Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
ELVIS HSV Solution 1 (Cell Fixative)	Flammable Liquid, Irritant	Eyes, Skin and Central Nervous System	Flammable Liquid (Category 2) Skin Irritation (Category 2) Eye Irritation (Category 2A) STOT SE (Category 3)
ELVIS HSV Solution 2T (Staining Buffer)	Toxic, Irritant	Eyes, Skin, and Unborn Child	Acute Toxicity, Dermal (Category 4) Acute Toxicity, Inhalation (Category 4) Eye Irritation (Category 2) Reproductive Toxicity (Category 1B)
40X PBS Concentrate	Toxic, Irritant	Eyes, Skin	Acute toxicity, Oral (Category 4) Acute aquatic toxicity (Category 3) Skin Irritation (Category 2) Eye Irritation (Category 2A) Chronic aquatic toxicity (Category 3)

GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
ELVIS HSV Solution 1 (Acetone 80%)	  Danger	H225 Highly flammable liquid and vapor. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness.	P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking. P233 Keep container tightly closed. P261 Avoid breathing vapors. P264 Wash hands thoroughly after handling. P271 Use in a well-ventilated area. P280 Wear protective gloves and safety glasses. P305+P351+p338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Section 2 – Hazards Identification (cont'd)

Component	Pictogram	Hazard Statements	Precautionary Statements
ELVIS HSV Solution 2T (DMF 10%)	  Danger	H312+H332: Harmful in contact with skin or if inhaled. H319 Causes serious eye irritation. H350 May cause cancer. H360: May damage fertility or the unborn child.	P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking. P233 Keep container tightly closed. P261 Avoid breathing vapors. P264 Wash hands thoroughly after handling. P280 Wear protective gloves and safety glasses. P308+P313: If exposed or concerned – get medical advice/attention. P305+P351+p338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
40X PBS Concentrate (Sodium Azide 4%)	 Warning	H302 Harmful if swallowed. H315 Causes skin irritation. H320 Causes eye irritation. H412 Harmful to aquatic life with long lasting effects.	P264 Wash hands thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves and safety glasses. P308+P313: If exposed or concerned – get medical advice/attention. P305+P351+p338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Supplemental Hazard Statements		1. Follow Universal Precautions when working with this kit. 2. Avoid release to the environment. 3. Sodium Azide is used as a preservative (0.1%) in the ELVIS Solution 3, ELVIS HSV Mounting Fluid and 40X PBS Concentrate. Avoid disposal of this material down sanitary or industrial plumbing systems. 4. Evan’s Blue is used in the ELVIS Solution 2T and ELVIS HSV Solution 3 at a concentration of <0.01%. Evans Blue is a possible carcinogen and may cause cancer (IARC Group 3). 5. N-Propylgallate is used in the ELVIS HSV Mounting Fluid at a concentration of 0.11%. May act as a skin or respiratory sensitizer to some individuals.	

Hazards Not Otherwise Classified (HNOC) or not covered by GHS:

ELVIS HSV Solution 1 (Cell Fixative): Repeated exposure may cause skin dryness or cracking (Acetone)

ELVIS HSV Solution 2T (Staining Buffer): Rapidly absorbs through skin (Dimethylformamide)

40X PBS Concentrate: May react with lead and copper plumbing to form highly explosive metal azides. Avoid disposal of this material down sanitary or industrial plumbing systems. (Sodium Azide)

Rapidly absorbed through the skin (Sodium Azide).

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
ELVIS HSV Solution 1 (Cell Fixative)	Acetone	67-64-1	200-662-2	80	15 mL
ELVIS HSV Solution 2T (Staining Buffer)	N,N-Dimethylformamide Sodium Desoxycholate	68-12-2 302-95-4	200-679-5 206-132-7	<10 1.2	15 mL
ELVIS HSV Solution 3	Sodium Azide	26628-22-8	247-852-1	0.1	3 mL
ELVIS HSV Mounting Fluid	Glycerol Sodium Azide n-Propylgallate	56-81-5 26628-22-8 121-79-9	200-289-5 247-852-1 204-498-2	60 0.1 0.11	7 mL
40X PBS Concentrate	Sodium Chloride Sodium Azide	7647-14-5 26628-22-8	231-598-3 247-852-1	<36 4	25 mL

NOTE: All of the above reagents, buffers, solutions or fluids are considered 'Mixtures'.

Section 4 – First Aid Measures

General Advice

Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance, as necessary.

If inhaled: Move the person to fresh air and support breathing as required.

In case of skin contact: Wash affected area with soap and water. Seek medical advice if irritation develops.

In case of eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical attention.

If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

ELVIS HSV Solution 1: Do NOT induce vomiting.

ELVIS HSV Solution 2T: Do NOT induce vomiting.

Note to Physicians: Treat symptomatically.

Section 5 – Fire Fighting Measures

General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

Extinguishing Media: For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.

General Fire Hazards: The components within this kit will not significantly contribute to the intensity of a fire.

Hazardous Combustion Products: No data available

Fire Fighting Equipment: Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the solutions, controls or reagents contained within this kit are unlikely.

<i>Personal Precautions:</i>	Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the solutions, controls or reagents within this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.
<i>Materials and Methods for Clean-Up:</i>	Soak up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.
<i>Recovery and Neutralization:</i>	Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
<i>Environmental Precautions:</i>	Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

Section 7 – Handling and Storage

Specific Use: For *In Vitro Diagnostic* use. Not for use by the general public.

Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with this kit. Keep out of reach of the general public.

Conditions for Safe Storage: To maintain efficacy, store according to the kit specific Package Insert instructions.

Incompatibilities To maintain efficacy, store according to the kit specific Package Insert instructions.

Section 8 – Exposure Controls and Personal Protection

Exposure Limits: No data available for the specific components within this kit.

Exposure Controls:

Engineering Measures Use with adequate ventilation.

Personal Protective Equipment

Respiratory Protection: None needed under normal conditions of use.

Hand Protection: Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.

Eye Protection: Wear safety glasses with side shields or goggles to prevent eye contact.

Skin and Body Protection: Use body protection appropriate for the task. A laboratory coat is recommended.

Hygiene Measures: Wash hands before and after use and at the end of the workday.

Environmental Exposure Controls

No special environmental controls are required.

Section 9 – Physical and Chemical Properties

Characteristic	ELVIS HSV Solution 1 (Cell Fixative)	ELVIS HSV Solution 2T (Staining Buffer)	40X PBS Concentrate
Boiling Point (°C)	No data available	No data available	No data available
Melting Point (°C)	No data available	No data available	No data available
Specific Gravity (H ₂ O = 1)	No data available	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available	No data available
pH	2	7.0-7.4	7.0-7.6
Solubility in Water	Soluble	Soluble	Soluble
Appearance and Odor	Clear liquid, mild odor	Green liquid, mild odor	Clear liquid, mild odor

Section 10 – Stability and Reactivity

Characteristic	ELVIS HSV Solution 1 (Cell Fixative)	ELVIS HSV Solution 2T (Staining Buffer)	40X PBS Concentrate
Component Stability	Stable	Stable	Stable
Hazard Reaction Potential	No data available	No data available	No data available
Conditions to Avoid	Heat, flames, sparks	No data available	No data available
Materials to Avoid	Bases, oxidizing agents, phosphorous oxychloride	Strong oxidizing agents	Metals, acids, dimethyl sulfate, halogenated hydrocarbons
Hazardous Decomposition Products	No data available	No data available	No data available

Section 11 – Toxicological Information

Acute Toxicity
Component Analysis – LD50 / LC50 / Irritation (No data available for specific kit components)

Chemical Name	CAS #	RTECS #	Information
Acetone	67-64-1	AL3150000	Oral LD ₅₀ Rat 5800 mg/kg
			Inhalation LC ₅₀ Rat-8h 50,100 mg/m ³
			Dermal LD ₅₀ Guinea Pig 7,426 mg/kg
N,N-Dimethylformamide (DMF)	68-12-2	LQ2100000	Oral LD ₅₀ Rat 2800 mg/kg
			Inhalation LC ₅₀ Rat-4h 9 mg/L
			Dermal LD ₅₀ Rabbit 1500 mg/kg
Sodium Azide	26628-22-8	VY8050000	Oral LD ₅₀ Rabbit 10 mg/kg
			Inhalation LC ₅₀ Rat 37 mg/m ³
			Dermal LD ₅₀ Rabbit 20 mg/kg

Section 11 – Toxicological Information (cont'd)

Potential Health Effects:

<u>ELVIS HSV Solution 1 (Cell Fixative):</u>		Flammable Liquid, Irritant
<u>ELVIS HSV Solution 2T (Staining Buffer):</u>		Toxic, Irritant
<u>40X PBS Concentrate:</u>		Toxic, Irritant
<i>Skin Corrosion/ Irritation:</i>	No data available	<i>Inhalation:</i> May cause respiratory tract irritation.
<i>Serious Eye Damage / Irritation:</i>	No data available	<i>Skin:</i> May cause skin irritation upon contact.
<i>Respiratory or Skin Sensitization:</i>	No data available	<i>Eyes:</i> May cause serious eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available	<i>Ingestion:</i> May be harmful if swallowed.

Carcinogenicity

<u>ELVIS HSV Solution 2T:</u>	N,N-Dimethylformamide	IARC Group 3: Not classifiable as to its carcinogenicity to humans.
	Evans Blue	IARC Group 3: Not classifiable as to its carcinogenicity to humans.
<u>ELVIS HSV Solution 3:</u>	Evans Blue	IARC Group 3: Not classifiable as to its carcinogenicity to humans.

Reproductive Toxicity

ELVIS HSV Solution 2T: Possible risk of congenital malformation in the fetus.

Teratogenicity

No data available

Specified Target Organ General Toxicity (GHS)

<i>Single Exposure (GHS):</i>	<u>ELVIS HSV Solution 1:</u>	May cause drowsiness or dizziness (Acetone).
<i>Repeated Exposure (GHS):</i>		No data available

Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

Synergistic Effects

No data available

Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components within this kit.

<u>ELVIS HSV Solution 1:</u>	Kidney – Irregularities – Based on Human Evidence (Acetone) Skin – Dermatitis – Based on Human Evidence
<u>ELVIS HSV Solution 2T:</u>	WARNING – intolerance for alcohol can occur up to 4 days after Dimethylformamide exposure. N,N-Dimethylformamide is considered to be a potent liver toxin.
<u>40X PBS Concentrate:</u>	Liver – irregularities – Based on Human Evidence (Sodium Azide)

Section 12 – Ecological Information

Ecotoxicity	<u>Acetone</u>	Toxicity to fish – LC ₅₀ Oncorhynchus mykiss (rainbow trout)	5,540 mg/L (96h)
		Toxicity to aquatic invertebrates – LC50 – Daphnia magna (water flea)	8,800 mg/L (48h)
		Toxicity to Algae	No data available

Mobility in Soil No data available

Persistence / Degradability No data available **PBT and vPvB Assessment** No data available

Bioaccumulation No data available

Other Adverse Effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment.

Section 13 – Disposal Considerations

Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge any of the solutions, reagents or controls into drains, water courses or onto the ground.

Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country (e.g., Canada, EU, Japan, etc.), federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

Section 14 – Transportation Information

U.S. Department of Transportation (DOT)

This product is regulated per 49 CFR 172.101, the U.S. department of transportation:

Shipping Name: Acetone	Hazard Class Number & Description: 3
UN ID Number: UN1090	DOT Label: Class 3 and Excepted Quantity marking
Packing Group: II	

International Air Transportation (IATA)

This product is regulated per International Air Transportation Association (IATA) Dangerous Goods Regulations:

Shipping Name: Acetone	Hazard Class Number & Description:
UN ID Number: UN1090	DOT Label: Class 3 and Excepted Quantity marking
Packing Group: II	Packaging Instruction: 960 (Y960)

International Maritime Dangerous Goods (IMDG)

This product is regulated per International Maritime Dangerous Goods (IMDG) Dangerous Goods Regulations:

Shipping Name: Acetone	Hazard Class Number & Description: 3
UN ID Number: UN1090	DOT Label: Class 3 and Excepted Quantity marking
Packing Group: II	

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards	<u>ELVIS HSV Solution 1 (Cell Fixative):</u>	Flammable Liquid, Irritant
	<u>ELVIS HSV Solution 2T (Staining Buffer):</u>	Toxic, Irritant
	<u>40X PBS Concentrate:</u>	Toxic, Irritant

SARA 302 The following chemicals are subject to reporting levels established by SARA Title III, Section 302:
 Sodium Azide CAS #: 26628-22-8 Revision Date: 2007-07-01

SARA 313 The following chemicals are subject to reporting levels established by SARA Title III, Section 313:
 Sodium Azide CAS #: 26628-22-8 Revision Date: 2007-07-01
 N,N-Diemethylformamide CAS #: 68-12-2 Revision Date: 2007-07-01

Section 15 – Regulatory Information (cont'd)

SARA 311/312

Acetone	CAS#: 67-64-1	Fire Hazard, Acute Health Hazard, Chronic Health Hazard
Sodium Azide	CAS #: 26628-22-8	Acute Health Hazard, Chronic Health Hazard
N,N-Diemethylformamide	CAS #: 68-12-2	Fire Hazard, Acute Health Hazard, Chronic Health Hazard

State Regulations

The following chemical(s) appear on one or more of the following state hazardous substances lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Acetone	67-64-1	Yes	Yes	Yes	Yes	Yes	Yes
N,N-Diemethylformamide	68-12-2	Yes	Yes	Yes	Yes	Yes	Yes
Sodium Azide	26628-22-8	Yes	Yes	Yes	Yes	Yes	Yes

California Prop 65: This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Canadian – WHMIS IDL

Chemical Name	CAS #	Minimum Concentration
Acetone	67-64-1	1%

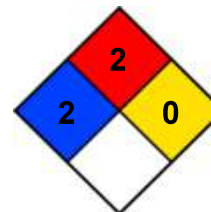
Additional Regulatory Information
Safety, Health and Environmental regulations/legislation specific for the mixture:

Not completed for this components contained within this kit.

Chemical Safety Assessment:

Not completed for this components contained within this kit.

HMIS Kit Classification:

NFPA Kit Classification:


Section 16 – Other Information

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SUPERCEDES: April 24, 2016

REVISIONS: Update to transportation information, removal of products SKT ELVIS-300.v2 and SKT ELVIS-60.v2, and general formatting changes.

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