

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: ELVIS HSV ID Test System

Catalog #: SK-ELVIS-100, SK-ELVIS-200, SK-ELVIS-500, SK-ELVIS-1000

Intended Use: A test system for the culture and identification 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) and ELVIS HSV Solution 2 (Staining Buffer); 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 2 (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)

GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
ELVIS HSV Solution 1 (Acetone 80%)		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 2 (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.
Supplemental Hazard Statements		1. Various antimicrobials are used within the ELVIS HSV Replacement Medium, including Amphotericin B, Penicillin and Streptomycin. Some or all of these antimicrobials may act as a sensitizer to some individuals at very low concentrations. 1. Follow Universal Precautions when working with this kit. 2. Avoid release to the environment.	

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 2 (Staining Buffer): Rapidly absorbs through skin (Dimethylformamide)

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	100: 26 mL 200: 2x26 mL 500: 130 mL 1000: 2x130 mL
ELVIS HSV Solution 2 (Staining Buffer)	N,N-Dimethylformamide Sodium Desoxycholate	68-12-2 302-95-4	200-679-5 206-132-7	<10 1.2	100: 26 mL 200: 2x26 mL 500: 130 mL 1000: 2x130 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 2:** 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.

- Personal Precautions:* 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.
- Materials and Methods for Clean-Up:* 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.
- Recovery and Neutralization:* Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
- Environmental Precautions:* 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

Section 7 – Handling and Storage (cont'd)

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 2 (Staining Buffer)
Boiling Point (°C)	No data available	No data available
Melting Point (°C)	No data available	No data available
Specific Gravity (H ₂ O = 1)	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available
pH	2	6 to 8
Solubility in Water	Soluble	Soluble
Appearance and Odor	Clear liquid, mild odor	Yellow liquid, mild odor

Section 10 – Stability and Reactivity

Characteristic	ELVIS HSV Solution 1 (Cell Fixative)	ELVIS HSV Solution 2 (Staining Buffer)
Component Stability	Stable	Stable
Hazard Reaction Potential	No data available	No data available
Conditions to Avoid	Heat, flames, sparks	No data available
Materials to Avoid	Bases, oxidizing agents, phosphorous oxychloride	Strong oxidizing agents
Hazardous Decomposition Products	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

Potential Health Effects:

ELVIS HSV Solution 1 (Cell Fixative): Flammable Liquid, Irritant

ELVIS HSV Solution 2 (Staining Buffer): 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

ELVIS HSV Solution 2: N,N-Dimethylformamide IARC Group 3: Not classifiable as to its carcinogenicity to humans.

Reproductive Toxicity

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

Teratogenicity

No data available

Specified Target Organ General Toxicity (GHS)

Single Exposure (GHS): ELVIS HSV Solution 1: May cause drowsiness or dizziness (Acetone).

Repeated Exposure (GHS): No data available

Section 11 – Toxicological Information (cont'd)

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.

ELVIS HSV Solution 1: Kidney – Irregularities – Based on Human Evidence (Acetone)
 Skin – Dermatitis – Based on Human Evidence (Acetone)

ELVIS HSV Solution 2: **WARNING** – intolerance for alcohol can occur up to 4 days after Dimethylformamide exposure. N,N-Dimethylformamide is considered to be a potent liver toxin.

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.

Effect on the Ozone Layer: Not dangerous for the ozone layer.

Greenhouse Effect: No data available

Effect on Waste Water Purification: No data available

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, controls, cultures or media 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 Limited Quantity marking
Packing Group: II	

Per CFR 173.150; SK-ELVIS-100 & SK-ELVIS-200 can be shipped as excepted quantities per table 2.6.A.

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	IATA Label: Class 3 and Limited Quantity marking
Packing Group: II	

Small quantities of Class 3 materials may be shipped as “Acetone” in accordance with Special Provisions A41 and A163, provided that the requirements of Section 2.6, “Dangerous Goods in Excepted Quantities” are met.

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	IMDG Label: Class 3 and Limited 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 2 (Staining Buffer):</u>	Toxic, Irritant

SARA 302 The following chemicals are subject to reporting levels established by SARA Title III, Section 302:
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.

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

SARA 311/312

Acetone	CAS#: 67-64-1	Fire Hazard, Acute Health Hazard, Chronic Health Hazard
N,N-Diemethylformamide	CAS #: 68-12-2	Fire Hazard, Acute Health Hazard, Chronic Health Hazard

Section 15 – Regulatory Information (cont'd)

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-Dimethylformamide	68-12-2	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%

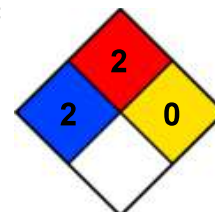
Additional Regulatory Information
Safety, Health and Environmental regulations/legislation specific for the mixture:

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

PREPARED BY: Quidel Corporation
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SUPERCEDES: New

REVISIONS: New

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