Section 1 – Product and Company Identification

Manufacturer Information

Quidel Corporation
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Athens, OH 45701
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Fax: 1.740.592.9820
Emergency #: 1.866.519.4752
Web: quidel.com
E-mail: qehs@quidel.com

Product Information

Product Name: ELVIS HSV ID Test System
Catalog #: I-SK-ELVIS-100 (acetone free)
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 2 (Staining Buffer); ELVIS HSV Cells and ELVIS HSV Replacement Medium purchased separately.

Section 2 – Hazards Identification

Emergency Overview

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>OSHA Hazards</th>
<th>Target Organs</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELVIS HSV Solution 2 (Staining Buffer)</td>
<td>Toxic, Irritant</td>
<td>Eyes, Skin, and Unborn Child</td>
<td>Acute Toxicity, Dermal (Category 4) Acute Toxicity, Inhalation (Category 4) Eye Irritation (Category 2) Reproductive Toxicity (Category 1B)</td>
</tr>
</tbody>
</table>

GHS Classification and Label Elements

<table>
<thead>
<tr>
<th>Component</th>
<th>Pictogram</th>
<th>Hazard Statements</th>
<th>Precautionary Statements</th>
</tr>
</thead>
</table>

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.
2. Follow Universal Precautions when working with this kit.
3. Avoid release to the environment.

Hazards Not Otherwise Classified (HNOC) or not covered by GHS:
Section 3 – Composition / Information on Ingredients

<table>
<thead>
<tr>
<th>Component</th>
<th>Chemical Name</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>Conc. (%)</th>
<th>Component Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELVIS HSV Solution 2 (Staining Buffer)</td>
<td>N,N-Dimethylformamide 68-12-2</td>
<td>200-679-5</td>
<td>&lt;10</td>
<td>1000: 2x130 mL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sodium Deoxycholate    302-95-4</td>
<td>206-132-7</td>
<td>1.2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 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 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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ELVIS HSV Solution 2 (Staining Buffer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity (H_2O = 1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Ether = 1)</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>6 to 8</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
</tr>
</tbody>
</table>
Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ELVIS HSV Solution 2 (Staining Buffer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component Stability</td>
<td>Stable</td>
</tr>
<tr>
<td>Hazard Reaction Potential</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>Strong oxidizing agents</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Section 11 – Toxicological Information

Acute Toxicity

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>RTECS #</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylformamide (DMF)</td>
<td>68-12-2</td>
<td>LQ2100000</td>
<td>Oral LD50 Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2800 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC50</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rat-4h 9 mg/L</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD50 Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1500 mg/kg</td>
</tr>
</tbody>
</table>

Potential Health Effects:

**ELVIS HSV Solution 2 (Staining Buffer):** Toxic, Irritant

- Skin Corrosion/ Irritation: No data available. Inhalation: May cause respiratory tract irritation.
- Serious Eye Damage / Irritation: No data available. Skin: May cause skin irritation upon contact.
- Respiratory or Skin Sensitization: No data available. Eyes: May cause serious eye irritation.
- Generative Cell Mutagenicity: No data available. Ingestion: 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): No data available
- Repeated Exposure (GHS): 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.

**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                              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)  Not Regulated for Transport
International Air Transportation (IATA)  Not Regulated for Transport
International Maritime Dangerous Goods (IMDG) Not Regulated for Transport

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards  ELVIS HSV Solution 2 (Staining Buffer):  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-Dimethylformamide  CAS #: 68-12-2  Revision Date: 2007-07-01
SARA 311/312
N,N-Dimethylformamide  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:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>CA</th>
<th>MA</th>
<th>MN</th>
<th>NJ</th>
<th>PA</th>
<th>RI</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylformamide</td>
<td>68-12-2</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Minimum Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>--</td>
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</tr>
</tbody>
</table>

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
12544 High Bluff Drive, Suite 200
San Diego, CA 92130

Supercedes: New

Revisions: New

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