Section 1 – Product and Company Identification

Manufacturer Information
Quidel Corporation
2005 East State Street, Suite 100
Athens, OH 45701
Phone: 1.800.874.1517
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 #: 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

<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 1 (Cell Fixative)</td>
<td>Flammable Liquid, Irritant</td>
<td>Eyes, Skin and Central Nervous System</td>
<td>Flammable Liquid (Category 2) Skin Irritation (Category 2) Eye Irritation (Category 2A) STOT SE (Category 3)</td>
</tr>
<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>
Section 2 – Hazards Identification (cont’d)

<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:

- **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

<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 1 (Cell Fixative)</td>
<td>Acetone</td>
<td>67-64-1</td>
<td>200-662-2</td>
<td>80</td>
<td>100: 26 mL 200: 2x26 mL 500: 130 mL 1000: 2x130 mL</td>
</tr>
<tr>
<td>ELVIS HSV Solution 2 (Staining Buffer)</td>
<td>N,N-Dimethylformamide Sodium Desoxycholate</td>
<td>68-12-2 302-95-4</td>
<td>200-679-5 206-132-7</td>
<td>&lt;10 1.2</td>
<td>100: 26 mL 200: 2x26 mL 500: 130 mL 1000: 2x130 mL</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 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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ELVIS HSV Solution 1 (Cell Fixative)</th>
<th>ELVIS HSV Solution 2 (Staining Buffer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting Point (°C)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity (H₂O = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Ether = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>2</td>
<td>6 to 8</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Clear liquid, mild odor</td>
<td>Yellow liquid, mild odor</td>
</tr>
</tbody>
</table>
Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ELVIS HSV Solution 1 (Cell Fixative)</th>
<th>ELVIS HSV Solution 2 (Staining Buffer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component Stability</td>
<td>Stable</td>
<td>Stable</td>
</tr>
<tr>
<td>Hazard Reaction Potential</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Heat, flames, sparks</td>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>Bases, oxidizing agents, phosphorous oxychloride</td>
<td>Strong oxidizing agents</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</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>Acetone</td>
<td>67-64-</td>
<td>AL3150000</td>
<td>Oral LD$_{50}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC$_{50}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD$_{50}$</td>
</tr>
<tr>
<td>N,N-Dimethylformamide (DMF)</td>
<td>68-12-2</td>
<td>LQ2100000</td>
<td>Oral LD$_{50}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC$_{50}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD$_{50}$</td>
</tr>
</tbody>
</table>

Potential Health Effects:

- **ELVIS HSV Solution 1 (Cell Fixative):** Flammable Liquid, Irritant
- **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):** 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 Acetone
Toxicity to fish – LC50 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
UN ID Number: UN1090
Packing Group: II

Hazard Class Number & Description: 3
DOT Label: Class 3 and Limited Quantity marking

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
UN ID Number: UN1090
Packing Group: II

Hazard Class Number & Description:
IATA Label: Class 3 and Limited Quantity marking

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
UN ID Number: UN1090
Packing Group: II

Hazard Class Number & Description: 3
IMDG Label: Class 3 and Limited Quantity marking

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards
ELVIS HSV Solution 1 (Cell Fixative): Flammable Liquid, Irritant
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-Diethylformamide 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-Diethylformamide 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>Acetone</td>
<td>67-64-1</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<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>Acetone</td>
<td>67-64-1</td>
<td>1%</td>
</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

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability, fitness for a particular purpose or of any other type, expressed or implied, with respect to products described or data or information provided, and we assume no liability resulting from the use of such products, data or information. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Quidel be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, howsoever arising, even if Quidel has been advised of the possibility of such damages.