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 and D³ Test System (Catalog #: 1-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 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

<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 2T (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>
<tr>
<td>40X PBS Concentrate</td>
<td>Toxic, Irritant</td>
<td>Eyes, Skin</td>
<td>Acute toxicity, Oral (Category 4) Acute aquatic toxicity (Category 3) Skin Irritation (Category 2) Eye Irritation (Category 2A) Chronic aquatic toxicity (Category 3)</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>
<tbody>
<tr>
<td>ELVIS HSV Solution 2T (DMF 10%)</td>
<td>![Danger]</td>
<td>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.</td>
<td>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,</td>
</tr>
</tbody>
</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. 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 ELVIISSolution 2T and ELVISHSV 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 (HNOCC) or not covered by GHS:**

**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

<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 2T</td>
<td>N,N-Dimethylformamide</td>
<td>68-12-2</td>
<td>200-679-5</td>
<td>&lt;10</td>
<td>15 mL</td>
</tr>
<tr>
<td></td>
<td>Sodium Desoxycholate</td>
<td>302-95-4</td>
<td>206-132-7</td>
<td>1.2</td>
<td></td>
</tr>
<tr>
<td>ELVIS HSV Solution 3</td>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>247-852-1</td>
<td>0.1</td>
<td>3 mL</td>
</tr>
<tr>
<td>ELVIS HSV Mounting Fluid</td>
<td>Glycerol</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>60</td>
<td>7 mL</td>
</tr>
<tr>
<td></td>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>247-852-1</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n-Propylgallate</td>
<td>121-79-9</td>
<td>204-498-2</td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>40X PBS Concentrate</td>
<td>Sodium Chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>&lt;36</td>
<td>25 mL</td>
</tr>
<tr>
<td></td>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>247-852-1</td>
<td>4</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 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.

**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.
Section 7 – Handling and Storage (cont’d)

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 2T (Staining Buffer)</th>
<th>40X PBS Concentrate</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>7.0-7.4</td>
<td>7.0-7.6</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Green liquid, mild odor</td>
<td>Clear liquid, mild odor</td>
</tr>
</tbody>
</table>
Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ELVIS HSV Solution 2T (Staining Buffer)</th>
<th>40X PBS Concentrate</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>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>Strong oxidizing agents</td>
<td>Metals, acids, dimethyl sulfate, halogenated hydrocarbons</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>N,N-Dimethylformamide (DMF)</td>
<td>68-12-2</td>
<td>LQ21000000</td>
<td>Oral LD50: Rat 2800 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC50: Rat-4h 9 mg/L</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD50: Rabbit 1500 mg/kg</td>
</tr>
<tr>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>VY80500000</td>
<td>Oral LD50: Rabbit 10 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC50: Rat 37 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD50: Rabbit 20 mg/kg</td>
</tr>
</tbody>
</table>

Potential Health Effects:

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

**40X PBS Concentrate:** 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 2T:** 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.

**ELVIS HSV Solution 3:** 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)

*Single Exposure (GHS):* No data available

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

**40X PBS Concentrate:**
Liver – irregularities – Based on Human Evidence (Sodium Azide)

Section 12 – Ecological Information

Ecotoxicity
No data available

Mobility in Soil
No data available

Persistence / Degradability
No data available

Bioaccumulation
No data available

PBT and vPvB Assessment
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)
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 2T (Staining Buffer):** Toxic, Irritant
- **40X PBS Concentrate:** Toxic, Irritant
Section 15 – Regulatory Information (cont’d)

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

SARA 311/312  
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:

<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-Diemethylformamide</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>
<tr>
<td>Sodium Azide</td>
<td>26628-22-8</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>N,N-Diemethylformamide</td>
<td>68-12-2</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  
REVISIONS: New  
SUPERCEDES: New  
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