Section 1. Identification of the Substance and the Company

1.1 Product Code: KDPGFX

Product Name: Diapharma Factor X Kit

1.2 Relevant identified uses of the substance or mixture and uses advised against:

Relevant identified uses: For in vitro diagnostic use.

1.3 Details of the Supplier of the Safety Data Sheet:

Company Name: DiaPharma Group Inc.
8948 Beckett Rd.
West Chester, OH 45069

Web site address: www.diapharma.com

Email: info@diapharma.com

1.4 Emergency telephone number:

Emergency Contact: Phone: +1 (513) 860-9324
Fax: +1 (513) 860-9635

Section 2. Hazards Identification

2.1 Classification of the Substance or Mixture:

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]:

- Acute Toxicity, Oral, Category 2
- Aquatic Acute Toxicity Category 1
- Aquatic Chronic Toxicity Category 1

2.2 Label Elements:

2.2.1 Labeling according to Regulation (EC) No 1272/2008 [CLP]:

GHS Signal Word: Warning

GHS Hazard Phrases:

- H300: Fatal if swallowed
- H319: Causes serious eye irritation
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long-lasting effects

GHS Precaution Phrases:

- P260: Do not breathe dust/fumes/gas/mist/vapours/spray.
- P262: Do not get in eyes, on skin, or on clothing.
- P264: Wash hands thoroughly after handling.
- P270: Do not eat, drink or smoke when using this product.
- P271: Use only outdoors or in a well-ventilated area.
- P273: Avoid release to the environment.
- P280: Wear protective gloves/protective clothing/eye protection/face protection.
- P284: In case of inadequate ventilation, wear respiratory protection.

GHS Response Phrases:

- P301+310: IF SWALLOWED: Immediately call a POISON CENTER/doctor
- P301+330: IF SWALLOWED: Rinse mouth.
- P302+352: IF ON SKIN: Wash with plenty of water
- P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P361+364: Take off immediately contaminated clothing and wash it before reuse.
P391: Collect spillage.

GHS Storage and Disposal Phrases:
Please refer to Section 7 for Storage and Section 13 for Disposal information

2.3 Adverse Human Health Effects and Symptoms:
Biohazard - Handle as if capable of transmitting infectious agents.
Material may be irritating to the mucous membranes and upper respiratory tract.
May be harmful by inhalation, ingestion, or skin absorption.
May cause respiratory irritation.
Toxic if inhaled or ingested.
To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Section 3. Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>Components (Chemical Name)/REACH Registration No.</th>
<th>CAS # / EC No.</th>
<th>Concentration</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Chloride</td>
<td>Calcium Chloride</td>
<td>10043-52-4 / 233-140-8</td>
<td>~40 – 50%</td>
<td>Eye Irrit. 2: H319</td>
</tr>
<tr>
<td></td>
<td>Sodium Azide</td>
<td>26628-22-8 / 247-852-1</td>
<td>~0 - 2%</td>
<td>Acute Tox.(O) 2: H300 Aquatic (A) 1: H400 Aquatic (C) 1: H410</td>
</tr>
<tr>
<td>Tris/ Poly Buffer</td>
<td>Tris / 01-2119957659-16</td>
<td>77-86-1 / 201-064-4</td>
<td>~0 - 2%</td>
<td>No data available.</td>
</tr>
<tr>
<td></td>
<td>Sodium Chloride / 01-2119485491-33</td>
<td>7647-14-5 / 231-598-3</td>
<td>~5 - 10%</td>
<td>No data available.</td>
</tr>
<tr>
<td></td>
<td>Sodium Azide</td>
<td>26628-22-8 / 247-852-1</td>
<td>~0 - 2%</td>
<td>Acute Tox.(O) 2: H300 Aquatic (A) 1: H400 Aquatic (C) 1: H410</td>
</tr>
<tr>
<td></td>
<td>Polybrene</td>
<td>28728-55-4 / 684-236-5</td>
<td>~0 – 2%</td>
<td>Acute Tox.(O) 4: H302</td>
</tr>
<tr>
<td>Russell's Viper Venom</td>
<td>Russell's Viper Venom</td>
<td>NA / NA</td>
<td>~40 –50%</td>
<td>No Data Available</td>
</tr>
<tr>
<td></td>
<td>Sodium Azide</td>
<td>26628-22-8 / 247-852-1</td>
<td>~0 - 2%</td>
<td>Acute Tox.(O) 2: H300 Aquatic (A) 1: H400 Aquatic (C) 1: H410</td>
</tr>
<tr>
<td>FXa Chromogenic Substrate</td>
<td>p-Nitroaniline</td>
<td>100-01-6 / 202-810-1</td>
<td>&lt;0.0001%</td>
<td>Acute Tox (O) 3: H331, H311, H301 Aquatic (R) 1: H373 Aquatic (C) 1: H412</td>
</tr>
</tbody>
</table>

Section 4. First Aid Measures

4.1 Description of First Aid Measures: No data available.

In Case of Inhalation: Move person to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

In Case of Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In Case of Eye Contact: Flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

In Case of Ingestion: Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.
Section 5. Fire Fighting Measures

5.1 Suitable Extinguishing Media: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.

Unsuitable Extinguishing Media: A solid water stream may be inefficient.

5.2 Flammable Properties and Hazards: No data available.

Flash Pt: No data.
Explosive Limits: LEL: No data. UEL: No data.
Autoignition Pt: No data.

Fire Fighting Instructions: As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental Release Measures

6.1 Protective Precautions, Protective Equipment and Emergency Procedures:
Avoid creating and breathing dust and provide adequate ventilation.
As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental Precautions: Take steps to avoid release into the environment, if safe to do so.

6.3 Methods and Material for Containment and Cleaning Up:
Contain spill and collect, as appropriate.
Transfer to a chemical waste container for disposal in accordance with local regulations.
After removal, flush contaminated area and all cleaning materials with a 10% bleach aqueous solution.

Section 7. Handling and Storage

7.1 Precautions To Be Taken in Handling: Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
Avoid prolonged or repeated exposure.

7.2 Precautions To Be Taken in Storing: Keep container tightly closed.
Store in accordance with information listed on the product insert.

Section 8. Exposure Controls/Personal Protection

8.1 Exposure Parameters:

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Britain EH40</th>
<th>France VL</th>
<th>Europe</th>
<th>OSHA TWA</th>
<th>ACGIH TWA</th>
<th>Other Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Chloride</td>
<td>Calcium Chloride</td>
<td>10043-52-4</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
</tr>
<tr>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>TWA: 0.1 mg/m3</td>
<td>TWA: 0.1 mg/m3</td>
<td>TWA: 0.1 mg/m3</td>
<td>No data.</td>
<td>CEIL: 0.29 mg/m3</td>
<td>No data.</td>
<td></td>
</tr>
<tr>
<td>Tris/ Poly Buffer</td>
<td>Tris</td>
<td>77-86-1</td>
<td>TWA: 5.0 mg/m3</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>7647-14-5</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
<td>No data.</td>
</tr>
<tr>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>TWA: 0.1 mg/m3</td>
<td>TWA: 0.1 mg/m3</td>
<td>TWA: 0.1 mg/m3</td>
<td>No data.</td>
<td>CEIL: 0.29 mg/m3</td>
<td>No data.</td>
<td></td>
</tr>
<tr>
<td>Russell's Viper Venom</td>
<td>Russell's Viper Venom</td>
<td>No Data</td>
<td>No Data</td>
<td>No Data</td>
<td>No Data</td>
<td>No Data</td>
<td>No Data</td>
<td>No Data</td>
</tr>
<tr>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>TWA: 0.1 mg/m3</td>
<td>TWA: 0.1 mg/m3</td>
<td>TWA: 0.1 mg/m3</td>
<td>No data.</td>
<td>CEIL: 0.29 mg/m3</td>
<td>No data.</td>
<td></td>
</tr>
<tr>
<td>FXa Chromogenic Substrate</td>
<td>p-Nitroaniline</td>
<td>100-01-6</td>
<td>VME: 3mg/m3</td>
<td>No Data</td>
<td>No Data</td>
<td>TWA: 6 mg/m3</td>
<td>No Data</td>
<td>No Data</td>
</tr>
</tbody>
</table>
8.2 Exposure Controls:

8.2.1 Engineering Controls (Ventilation etc.): Use process enclosures, local exhaust ventilation or other engineering controls to control airborne levels below recommended exposure limits.

8.2.2 Personal protection equipment:

- **Eye Protection:** Safety glasses
- **Protective Gloves:** Compatible chemical-resistant gloves
- **Other Protective Clothing:** Lab coat
- **Respiratory Equipment (Specify Type):** NIOSH approved respirator, as conditions warrant.
- **Work/Hygienic/Maintenance Practices:** Do not take internally.
  Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower.
  Wash thoroughly after handling.

### Section 9. Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

- **Physical States:** [ ] Gas [X] Liquid [X] Solid
- **Appearance and Odor:** Solid
- **Melting Point:** No data.
- **Boiling Point:** No data.
- **Flash Pt:** No data.
- **Evaporation Rate:** No data.
- **Explosive Limits:** LEL: No data. UEL: No data.
- **Vapor Pressure (vs. Air or mm Hg):** No data.
- **Vapor Density (vs. Air = 1):** No data.
- **Specific Gravity (Water = 1):** No data.
- **Solubility in Water:** No data.
- **Autoignition Pt:** No data.

9.2 Other Information

- **Percent Volatile:** No data

### Section 10. Stability and Reactivity

10.1 Reactivity: No data available.
10.2 Stability: Unstable [ ] Stable [X]
10.3 Stability Note(s): Stable if stored in accordance with information listed on the product insert.
10.4 Conditions To Avoid: No data available.
10.5 Incompatibility – Materials To Avoid: No data available.
10.6 Hazardous Decomposition Or Byproducts: No data available.

### Section 11. Toxicological Information

11.1 Information on Toxicological Effects: The toxicological effects of this product have not been thoroughly studied.

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>Chemical Name</th>
<th>CAS #</th>
<th>NTP</th>
<th>IARC</th>
<th>ACGIH</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Chloride</td>
<td>Calcium Chloride</td>
<td>10043-52-4</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
</tbody>
</table>
### Section 12. Ecological Information

12.1 Toxicity: Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.

12.2 Persistence and Degradability: No data available.

12.3 Bioaccumulative Potential: No data available.

12.4 Mobility in Soil: No data available.

12.5 Results of PBT and vPvB assessment: No data available.

12.6 Other adverse effects: No data available.

### Section 13. Disposal Considerations

13.1 Waste Disposal Method: Dispose in accordance with local, state, and federal regulations.

### Section 14. Transport Information

14.1 LAND TRANSPORT (US DOT):
   - DOT Proper Shipping Name: Not dangerous goods.
   - DOT Hazard Class:
   - UN/NA Number:

14.2 LAND TRANSPORT (European ADR/RID):
   - ADR/RID Shipping Name: Not dangerous goods.
   - UN Number:
   - Hazard Class:

14.3 AIR TRANSPORT (ICAO/IATA):
   - ICAO/IATA Shipping Name: Not dangerous goods.
   - Additional Transport Information: Transport in accordance with local, state, and federal regulations.

### Section 15. Regulatory Information

#### EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

<table>
<thead>
<tr>
<th>CAS #</th>
<th>Hazardous Components (Chemical Name)</th>
<th>S. 302 (EHS)</th>
<th>S. 304 RQ</th>
<th>S. 313 (TRI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10043-52-4</td>
<td>Calcium Chloride</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>26628-22-8</td>
<td>Sodium Azide</td>
<td>Yes 500 LB</td>
<td>Yes 1000 LB</td>
<td>Yes</td>
</tr>
<tr>
<td>77-86-1</td>
<td>Tris</td>
<td>No</td>
<td>No</td>
<td>Yes-Cat. N106</td>
</tr>
<tr>
<td>CAS #</td>
<td>Hazardous Components (Chemical Name)</td>
<td>Other US EPA or State Lists</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------</td>
<td>------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10043-52-4</td>
<td>Calcium Chloride</td>
<td>CAA HAP, ODC: No; CWA NPDES: No; TSCA: Yes - Inventory; CA PROP.65: No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26628-22-8</td>
<td>Sodium Azide</td>
<td>CAA HAP, ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>77-86-1</td>
<td>Tris</td>
<td>CAA HAP, ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7647-14-5</td>
<td>Sodium Chloride</td>
<td>CAA HAP, ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28728-55-4</td>
<td>Polybrene</td>
<td>CAA HAP, ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td>Russell’s Viper Venom</td>
<td>CAA HAP, ODC: No; CWA NPDES: No; TSCA: Yes - Inventory; CA PROP.65: No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100-01-6</td>
<td>p-Nitroaniline</td>
<td>CAA HAP, ODC: No; CWA NPDES: No; TSCA: Yes - Inventory; CA PROP.65: No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Information Statement:** This SDS was prepared in accordance with 29 CFR 1910.1200 and Regulation (EC) No.1272/2008

**Section 16. Other Information**

**Revision Date:** 08/14/2019

**Additional Information About This Product:** No data available.

**Company Policy or Disclaimer:**

DISCLAIMER: This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their purposes.