

According to Regulation (EC) No. 1907/2006 as amended by (EC) No. 1272/2008

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

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

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:

Kit Component	Chemical Name	CAS #	Britain EH40	France VL	Europe	OSHA TWA	ACGIH TWA	Other Limits
Calcium Chloride	Calcium Chloride	10043-52-4	No data.	No data.	No data.	No data.	No data.	No data.
	Sodium Azide	26628-22-8	TWA: 0.1 mg/m3 () STEL: 0.3 mg/m3 ()	TWA: 0.1 mg/m3 STEL: 0.3 mg/m3	TWA: 0.1 mg/m3 STEL: 0.3 mg/m3	No data.	CEIL: 0.29 mg/m3	No data.
Tris/ Poly Buffer	Tris	77-86-1	TWA: 5.0 mg/m3	TWA: 5 mg/m3	No data.	TWA: 5 mg/m3	CEIL: 5 mg/m3	No data.
	Sodium Chloride	7647-14-5	No data.	No data.	No data.	No data.	No data.	No data.
	Sodium Azide	26628-22-8	TWA: 0.1 mg/m3 () STEL: 0.3 mg/m3 ()	TWA: 0.1 mg/m3 STEL: 0.3 mg/m3	TWA: 0.1 mg/m3 STEL: 0.3 mg/m3	No data.	CEIL: 0.29 mg/m3	No data.
	Polybrene	28728-55-4	No data.	No data.	No data.	No data.	No data.	No data.
Russell's Viper Venom	Russell's Viper Venom	NA	No Data	No Data	No Data	No Data	No Data	No Data
	Sodium Azide	26628-22-8	TWA: 0.1 mg/m3 () STEL: 0.3 mg/m3 ()	TWA: 0.1 mg/m3 STEL: 0.3 mg/m3	TWA: 0.1 mg/m3 STEL: 0.3 mg/m3	No data.	CEIL: 0.29 mg/m3	No data.
FXa Chromogenic Substrate	p-Nitroaniline	100-01-6	No Data	VME: 3mg/m3 STEL: NA	No Data	TWA: 6 mg/m3	No Data	No Data

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 Liquid 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
10.3 Stability Note(s): Stable if stored in accordance with information listed on the product insert.
Polymerization: Will occur Will not occur
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.

Kit Component	Chemical Name	CAS #	NTP	IARC	ACGIH	OSHA
Calcium Chloride	Calcium Chloride	10043-52-4	n.a.	n.a.	n.a.	n.a.
	Sodium Azide	26628-22-8	n.a.	n.a.	A4	n.a.

Tris/ Poly Buffer	Tris	77-86-1	n.a.	n.a.	n.a.	n.a.
	Sodium Chloride	7647-14-5	n.a.	n.a.	n.a.	n.a.
	Sodium Azide	26628-22-8	n.a.	n.a.	A4	n.a.
	Polybrene	28728-55-4	n.a.	n.a.	n.a.	n.a.
Russell's Viper Venom	Russell's Viper Venom	NA	n.a.	n.a.	n.a.	n.a.
	Sodium Azide	26628-22-8	n.a.	n.a.	A4	n.a.
FXa Chromogenic Substrate	p-Nitroaniline	100-01-6	n.a.	n.a.	n.a.	n.a.

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

CAS #	Hazardous Components (Chemical Name)	S. 302 (EHS)	S. 304 RQ	S. 313 (TRI)
10043-52-4	Calcium Chloride	No	No	No
26628-22-8	Sodium Azide	Yes 500 LB	Yes 1000 LB	Yes
77-86-1	Tris	No	No	Yes-Cat. N106
7647-14-5	Sodium Chloride	No	No	No
28728-55-4	Polybrene	No	No	No
NA	Russell's Viper Venom	No	No	No

100-01-6	p-Nitroaniline	No	No	NO
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CAS #	Hazardous Components (Chemical Name)	Other US EPA or State Lists
10043-52-4	Calcium Chloride	CAA HAP,ODC: No; CWA NPDES: No; TSCA: Yes - Inventory; CA PROP.65: No
26628-22-8	Sodium Azide	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No
77-86-1	Tris	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No
7647-14-5	Sodium Chloride	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No
28728-55-4	Polybrene	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No
NA	Russell's Viper Venom	CAA HAP,ODC: No; CWA NPDES: No; TSCA: Yes - Inventory; CA PROP.65: No
100-01-6	p-Nitroaniline	CAA HAP,ODC: No; CWA NPDES: No; TSCA: Yes - Inventory; CA PROP.65: No

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.