SAFETY DATA SHEET
FACTOR XA 10 X 71 NKAT

IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: Factor Xa 10 x 71 nkat
Product Number: 0082098539
Use of the product: For Laboratory Use Only

Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), Italy

DISTRIBUTOR US/CANADA:
DiaPharma Group, Inc.
8948 Beckett Rd.
West Chester, OH 45069 (USA)

E-mail address of the competent person: infosds@mail.ilww.it
Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE PRODUCT

<table>
<thead>
<tr>
<th>P/N</th>
<th>Mixture name</th>
<th>Mixture classification</th>
<th>Mixture classification</th>
<th>Kit configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>000650515</td>
<td>Factor Xa 71 nkat</td>
<td>Respiratory or skin sensitization, cat. 1</td>
<td>Resp Sens. 1, H334</td>
<td>10 x 71 nkat</td>
</tr>
</tbody>
</table>

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user’s responsibility for the product’s safe use, the product’s suitability for the intended use and the product’s safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl
SECTION 1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: Factor Xa 71 nkat
Product Number: 000650515

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.
Uses advised against: There are no specific uses advised against.

1.3 Company identification:

MANUFACTURER: Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU: Via Leonardo da Vinci, 36
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E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone:

+44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:


Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.


<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Hazard category</th>
<th>Hazard statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESPIRATORY OR SKIN SENSITISATION</td>
<td>cat. 1</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled. (H334)</td>
</tr>
</tbody>
</table>

For exposure limits see Ch. 8

Potential adverse physicochemical, human health and environmental effects
(see also Ch. 9-12)

The product may cause allergy or asthma symptoms or breathing difficulties if inhaled.
Under normal conditions of use, the mixture does not cause adverse effects to the environment.

2.2 Label elements:

According to Regulation (EC) No 1272/2008

<table>
<thead>
<tr>
<th>Hazard pictogram(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Hazard pictogram" /></td>
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</table>

<table>
<thead>
<tr>
<th>Signal word(s):</th>
</tr>
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<tbody>
<tr>
<td>Danger</td>
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</table>

<table>
<thead>
<tr>
<th>Hazard statement(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled. (H334)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Precautionary statement(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid breathing dust/fume. (P261)</td>
</tr>
<tr>
<td>In case of inadequate ventilation wear respiratory protection. (P284)</td>
</tr>
<tr>
<td>If INHALED: Remove person to fresh air and keep comfortable for breathing. (P304 + P340)</td>
</tr>
<tr>
<td>If experiencing respiratory symptoms: Call a POISON CENTER/doctor. (P342 + P311)</td>
</tr>
<tr>
<td>Dispose of contents/container in accordance with local/regional/national/international regulation. (P501)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other labeling details:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contains Factor Xa.</td>
</tr>
<tr>
<td>Up to 11.3% of the mixture consists of components of unknown acute toxicity (oral, dermal, inhalation) for the human health. Up to 7.4% of the mixture consists of components of unknown hazard to the aquatic environment.</td>
</tr>
</tbody>
</table>
according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

**Hazard pictogram(s):**

- ![](image)

**Signal word(s):** Danger

**Hazard statement(s):**

Avoid breathing dust/fume. 
[In case of inadequate ventilation] wear respiratory protection. 
IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. 
If experiencing respiratory symptoms: Call a POISON CENTER/doctor. 
Dispose of contents/container in accordance with local/regional/national/international regulation.

**Precautionary statement(s):**

Avoid breathing dust/fume. 
If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice immediately (show the SDS or the label were possible).

**Other labeling details:**

Up to 11.3% of the mixture consists of components of unknown acute toxicity (oral, dermal, inhalation) for the human health. Up to 7.4% of the mixture consists of components of unknown hazard to the aquatic environment.

### 2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

**Warning:**

The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.

Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Composition:** solid containing organic and inorganic components, bovine material.

### 3.1 Hazardous components

<table>
<thead>
<tr>
<th>Name</th>
<th>EINECS/ ELINCS n°</th>
<th>CAS n°</th>
<th>Conc. % w/w*</th>
<th>Classification 29 CFR 1910.1200 (HCS)</th>
<th>Classification HPR (WHMIS 2015)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor Xa Index N. (Annex VI of CLP Reg.): 647-014-00-9 - proteases with the exception of those specified elsewhere in this Annex</td>
<td>Not available</td>
<td>Not available</td>
<td>&lt; 7%</td>
<td>Skin Corrosion/Irritation, cat. 2</td>
<td>Skin Irrit. 2, H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye damage/Eye Irritation, cat. 2A</td>
<td>Eye Irrit. 2, H319</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Specific target organ Toxicity – Single Exposure, cat. 3</td>
<td>STOT SE 3, H335</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitization-Respiratory, cat. 1</td>
<td>Resp. Sens. 1, H334</td>
</tr>
<tr>
<td>Tris Hydrochloride</td>
<td>214-684-5</td>
<td>1185-53-1</td>
<td>&lt; 5 %</td>
<td>Skin Corrosion/Irritation, cat.2</td>
<td>Skin Irrit. 2, H315</td>
</tr>
<tr>
<td>Tris-Hydroxymethyl aminomethane (Tris Amino)</td>
<td>201-064-4</td>
<td>77-86-1</td>
<td>&lt; 0.5%</td>
<td>Skin Corrosion/Irritation, cat. 2</td>
<td>Skin Irrit. 2, H315</td>
</tr>
</tbody>
</table>

* A range may be indicated, considering batch-to-batch variation.

For exposure limits see Ch. 8, for hazard statements text see Ch. 16.

The mixture does not contain substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA. See Section 11 and 15.

### SECTION 4. FIRST AID MEASURES

#### 4.1 Description of first aid measures

**Ingestion:** If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

**Inhalation exposure:** If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice immediately (show the SDS or the label were possible).
Contact with skin: Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute: Inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause irritation to the mucous membranes and upper respiratory tract. Skin: May be irritant for skin. Contains Bovine serum albumin (BSA), that might cause allergic skin reaction. Eyes: May cause irritation. Ingestion: may cause irritation to the gastrointestinal mucous membranes.

Delayed: Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring: Based on the assessment of risk of hazardous chemical agents, the competent person will settle the appropriate medical surveillance protocol, in accordance with the national/Community legislation, in order to protect the health status of the workers.

Antidotes, if known: Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray or regular foam, CO2, dry powder.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, HCl, HF, NOx.

5.3 Advice for firefighters

Protective actions: Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Equipment for self-protection: Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed with the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

For emergency responders: Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.

6.2 Environmental precautions

Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

6.3 Methods and material for containment and cleaning up

Soak up with inert absorbent material, and clean with plenty of water. collect spilled material in containers. Send to the storage waiting for disposal procedures.

6.4 Reference to other sections

See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Handle in a well ventilated place, and away from sparkles and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8). Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.
7.2 Conditions for safe storage, incompatibilities

Recommended temperature: store at 2-8°C. Avoid light exposure and keep away from heat sources. Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release. Keep away from food and drinks.

7.3 Specific end use

Factor Xa 71 nkat is intended for in vitro diagnostic use. The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled. However, the material should be treated as potentially infectious. Avoid inhalation of product. Use the product in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Community/National occupational exposure limit values: Not established.
Community/National biological exposure limit values: Not established.
DNEL values (components): Not established.
PNEC values (components): Not established.
The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipment must be adopted, complying with the relevant technical national/international standards.

8.2.2 Individual protection measures, such as Personal Protective Equipment (PPE)

Respiratory protection: Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter, Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).

Skin protection: Protective clothing, rubber gloves.

Eye protection: Safety glasses.

Hand protection: Protective gloves.

Other protective systems: Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3 Environmental exposure controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Value</th>
<th>Related to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance:</td>
<td>solid</td>
</tr>
<tr>
<td>Odor:</td>
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</tr>
<tr>
<td>Color:</td>
<td>White to off-white</td>
</tr>
<tr>
<td>pH:</td>
<td>not available</td>
</tr>
<tr>
<td>Flammability:</td>
<td>not available</td>
</tr>
<tr>
<td>Explosive properties:</td>
<td>not available</td>
</tr>
<tr>
<td>Oxidizing properties:</td>
<td>not available</td>
</tr>
<tr>
<td>Density:</td>
<td>Not available</td>
</tr>
<tr>
<td>Solubility:</td>
<td>not available</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>Soluble</td>
</tr>
<tr>
<td>Melting point/range:</td>
<td>not available</td>
</tr>
</tbody>
</table>

9.2 Other information

not available
SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity
This mixture is considered not reactive under the normal conditions of the usage.

10.2 Chemical stability
The product is stable until the expiration date shown on the box and on the labels when stored at 2 – 8 °C.

10.3 Possibility of hazardous reactions
Not foreseen.

10.4 Conditions to avoid:
Keep away from heat, water, humidity, and light.

10.5 Incompatible materials
Strong oxidising agents.

10.6 Hazardous decomposition products:
Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, HCl, HF, NOx.

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided below.

11.1 Information on toxicological effects
Symptoms and effects for each route of exposure:

Dermal: May cause skin irritation. Contains bovine serum albumin; might cause mild cause allergic skin reaction

Ingestion: Ingestion may cause irritation to the gastrointestinal mucous membranes.

Inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause irritation to the mucous membranes and upper respiratory tract.

Contact with eyes: May cause eye irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion):

Tris Amino: is not metabolized appreciably and is eliminated by the kidneys. Ionized tromethamine is excreted by kidney, so the effect is that of excretion of hydrogen ions. Elimination of drug from body is entirely by renal excretion. It is not known whether tromethamine is distributed into human milk. (1)

Acute toxicity Value m.u. Effects Related to
Oral: LD50 (rat) > 3,000 mg/kg
Dermal: LD50 (rat) > 5,000 mg/kg
Inhalation: not available
Other: not available

Tris Amino: Tromethamine was a mild irritant to rabbits at 25% with a pH of 10.8. At 40%, tromethamine was not irritating. Intradermal injections of tromethamine were severely irritating to rabbits at pH 10.4 but were only mildly irritating at pH 7.4. The supporting substance 2-Amino-2-methyl-1-Propanol (AMP) was found to be irritating to rabbits, with burrowing lesions noted when applied to abraded skin sites; there was mild irritation noted when applied to unabraded skin. (2)

Tris Hydrochloride: irritant to skin (read across from Tris Amino).

Serious eye damage/ irritation Tris Amino (100%) was not an ocular irritant when administered to rabbits. (2)
Tris Hydrochloride: mild eye irritant in rabbits. (5)

Sensitization:
Skin sensitization: Tris Amino: The supporting chemical AMP is not sensitizing to guinea pig skin. (2)
Tris Hydrochloride: Not a sensitizer in experimental animals. (5)

Bovine serum albumin (BSA), which is present in bovine plasma, could develop allergic skin reactions in laboratory workers after dealing with BSA powder. Based on the available data, the criteria for classification are not satisfied.
Respiratory sensitization: Bovine serum albumin (BSA), which is present in bovine plasma, could develop allergic reactions in laboratory workers after dealing with BSA powder. It is reported a case of occupational asthma and rhinitis in a laboratory worker caused by the inhalation of 100% BSA powder. The patient had a high serum-specific IgE level to BSA, and experienced severe systemic reactions, including eye itching, conjunctivitis, rhinorrhea, nasal obstruction, sneezing, shortness of breath, bronchospasm and decreased blood pressure. It was suggested an IgE-mediated response as the pathogenic mechanism. Based on the available data, the criteria for classification are not satisfied.

CMR effects

Germ cell mutagenicity: Tris Amino: The supporting chemical, AMP, was not mutagenic to bacteria and mammalian cells in vitro, and did not induce micronuclei in mice in vivo.

Reproductive toxicity: Tris Amino: In an oral gavage combined reproductive/developmental toxicity screening test in rats no effects on reproductive or developmental parameters were observed at the doses tested; the NOAEL for reproductive and developmental toxicity is 1000 mg/kg-day, the highest dose tested. (2)

Carcinogenesis: Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

<table>
<thead>
<tr>
<th>Substance</th>
<th>OSHA</th>
<th>IARC</th>
<th>NTP</th>
</tr>
</thead>
<tbody>
<tr>
<td>No component listed</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tris Amino: based on the available data, the substance is not carcinogenic. (4)

STOT – single exposure

STOT – repeated exposure

Aspiration hazards

Other information:

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

12.1 Toxicity

<table>
<thead>
<tr>
<th>Related to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tris Amino</td>
</tr>
<tr>
<td>Tris HCl</td>
</tr>
</tbody>
</table>

12.2 Persistence and degradability: Tris Amino is not readily biodegradable is expected to have moderate persistence. (1)

12.3 Bioaccumulation potential: Tris-Hydroxymethyl aminomethane is expected to have low bioaccumulation potential. (1)

12.4 Mobility in soil: Tris Amino is expected to have high mobility in soil. (2)

12.5 Results of PBT and vPvB assessment

Not performed.
12.6 Other toxic effects: Not available.

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations


Restriction of use: none
Substance(s) under authorization: none

US Federal Regulations:

<table>
<thead>
<tr>
<th>State</th>
<th>Components listed</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massachusetts</td>
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</tr>
<tr>
<td>New York</td>
<td>No component listed</td>
<td></td>
</tr>
<tr>
<td>New Jersey</td>
<td>No component listed</td>
<td></td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>No component listed</td>
<td></td>
</tr>
</tbody>
</table>

California Prop. 65

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>Cancer</th>
<th>Reproductive</th>
<th>NSRL or MADL (µg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean Water Act (CWA) 307</td>
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<td></td>
</tr>
<tr>
<td>Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Clean Air Act Section 602 Class I Substances</td>
<td>No component listed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean Air Act Section 602 Class II Substances</td>
<td>No component listed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DEA List I Chemicals (Precursor Chemicals)</td>
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</tr>
<tr>
<td>DEA List II Chemicals (Essential Chemicals)</td>
<td>No component listed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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FACTOR XA 71 NKAT

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FACTOR XA 71 NKAT
Revision: 01
CO: 460149
Edited on: 10/27/2015

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.
Information related to the Regulation EC/1272/2008:

Hazard statement(s):
- H315: Causes skin irritation.
- H319: Causes serious eye irritation.
- H335: May cause respiratory irritation.
- H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015):

<table>
<thead>
<tr>
<th>Classification</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled. (H334)</td>
<td>Cut off method</td>
</tr>
</tbody>
</table>

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references:
1. HSDB Hazardous Substances Databank, Tromethamine
4. TEST PLAN For Tris(hydroxymethyl)aminomethane (77-86-1) Submitted to the U.S. Environmental Protection Agency Under the High Production Volume (HPV) Chemicals Challenge Program The Dow Chemical Company Midland, Michigan, 48674
6. Sigma Aldrich, SDS for Tromethamine Hydrochloride, Version 5.0, revision date 17.10.2013
7. http://e-aair.org - Allergy, Asthma and Immunology Research (AAIR) 2009, October, Occupational asthma caused by inhalation of bovine serum albumin powder, Case report