1. Identification

Product identifier: FRAXIPARINE INJECTION

Other means of identification: Not available.

Synonym(s):
- FRAXIPARINE FORTE PRE-FILLED SYRINGE
- FRAXIFORTE PRE-FILLED SYRINGE
- FRAXIPARIN PRE-FILLED SYRINGE
- FRAXIPARINA PRE-FILLED SYRINGE
- FRAXODI PRE-FILLED SYRINGE
- HEPARIN CALCIUM, FORMULATED PRODUCT

Recommended use: Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions: No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer:
GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS - TRANSPORT EMERGENCIES:
US / International toll call +1 703 527 3887 available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards:
Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements:
Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC):
Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEPARIN CALCULUM</td>
<td>HEPARIN (INN) CALCIUM, HEPARIN, CALCIUM SALT, CALCIUM HEPARINATE, HEPACARIN, NADROPARIN CALCIUM, GLUCOSAMINOGLYCANE SULFATED (CALCIUM SALT), HEPARIN CALCULUM FROM PORCINE INTESTINAL MUCOSA, GW843216A</td>
<td>37270-89-6</td>
<td>3.0 - 8.0</td>
</tr>
</tbody>
</table>
### 4. First-aid measures

#### Inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

#### Skin contact

Immediately flush skin with plenty of water. Remove and isolate contaminated clothing and shoes. Get medical attention if symptoms occur.

#### Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

#### Ingestion

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately.

#### Most important symptoms/effects, acute and delayed

The following adverse effects have been noted with therapeutic use of this material: impaired blood coagulation; bleeding.

#### Indication of immediate medical attention and special treatment needed

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

#### General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

### 5. Fire-fighting measures

#### Suitable extinguishing media

- Water fog
- Foam
- Dry chemical powder
- Carbon dioxide (CO2)

#### Unsuitable extinguishing media

None known.

#### Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

#### Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

#### Fire-fighting equipment/instructions

Move containers from fire area if you can do so without risk.

#### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

#### General fire hazards

Expected to be non-combustible.

### 6. Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.

#### Methods and materials for containment and cleaning up

- Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.
- Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

#### Environmental precautions

- Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
- Avoid discharge into drains, water courses or onto the ground.
7. Handling and storage

Precautions for safe handling
Avoid prolonged exposure. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities
Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>GSK Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEPARIN CALCIUM (CAS 37270-89-6)</td>
<td>8 HR TWA</td>
<td>500 mcg/m3</td>
</tr>
<tr>
<td></td>
<td>OHC</td>
<td>2</td>
</tr>
</tbody>
</table>

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALCIUM HYDROXIDE (CAS 1305-62-0)</td>
<td>PEL</td>
<td>5 mg/m3</td>
<td>Respirable fraction.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mg/m3</td>
<td>Total dust.</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALCIUM HYDROXIDE (CAS 1305-62-0)</td>
<td>TWA</td>
<td>5 mg/m3</td>
</tr>
</tbody>
</table>

US. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALCIUM HYDROXIDE (CAS 1305-62-0)</td>
<td>TWA</td>
<td>5 mg/m3</td>
</tr>
</tbody>
</table>

Biological limit values
No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls
An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Eye/face protection
Not normally needed. If contact is likely, safety glasses with side shields are recommended. Eye wash fountain is recommended.

Hand protection
The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

Other
Not normally needed.

Respiratory protection
No personal respiratory protective equipment normally required.

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations
An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Wash contaminated clothing before reuse.

9. Physical and chemical properties

Appearance

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Form</th>
<th>Color</th>
<th>Odor</th>
<th>Odor threshold</th>
<th>pH</th>
<th>Melting point/freezing point</th>
<th>Initial boiling point and boiling range</th>
<th>Flash point</th>
<th>Evaporation rate</th>
<th>Flammability (solid, gas)</th>
</tr>
</thead>
</table>
Upper/lower flammability or explosive limits

Flammability limit - lower (%)
Not available.

Flammability limit - upper (%)
Not available.

Explosive limit - lower (%)
Not available.

Explosive limit - upper (%)
Not available.

Vapor pressure
Not available.

Vapor density
Not available.

Relative density
Not available.

Solubility (water)
Not available.

Partition coefficient (n-octanol/water)
Not available.

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

10. Stability and reactivity

Reactivity
Not available.

Chemical stability
Material is stable under normal conditions. DO NOT FREEZE - dispose of properly if frozen.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
Contact with incompatible materials.

Incompatible materials
Strong oxidizing agents.

Hazardous decomposition products
Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion
Health injuries are not known or expected under normal use.

Inhalation
Health injuries are not known or expected under normal use.

Skin contact
Health injuries are not known or expected under normal use.

Eye contact
Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Symptoms related to the physical, chemical and toxicological characteristics
The following adverse effects have been noted with therapeutic use of this material: impaired blood coagulation; bleeding.

Information on toxicological effects

Acute toxicity
Health injuries are not known or expected under normal use.

Components

<table>
<thead>
<tr>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>7340 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>&gt; 5000 mg/kg</td>
</tr>
</tbody>
</table>

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation
Health injuries are not known or expected under normal use.

Serious eye damage/eye irritation
Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization
Not available.

Skin sensitization
Health injuries are not known or expected under normal use.
Sensitization
HEPARIN CALCIUM SAR / QSAR, DEREK, Lhasa, UK
Result: No structural alerts identified.

Germ cell mutagenicity
Health injuries are not known or expected under normal use. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity
HEPARIN CALCIUM
Ames Assay, GLP assay; Literature data
Result: Negative
Micronucleus Assay, Literature data
Result: Negative
Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay; Literature data
Result: Negative
mammalian cell mutation assay (CHO/HGPRT forward mutation assay), Literature data
Result: Negative

Carcinogenicity
Health injuries are not known or expected under normal use. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

Reproductive toxicity
Health injuries are not known or expected under normal use.

Specific target organ toxicity - single exposure
None known.

Specific target organ toxicity - repeated exposure
None known.

Aspiration hazard
Not available.

Chronic effects
None known.

Further information
Not available.

12. Ecological information
Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAIUM HYDROXIDE (CAS 1305-62-0)</td>
<td>Fish</td>
<td>EC50, Mosquito fish (Adult Gambusia affinis)</td>
</tr>
</tbody>
</table>

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Other adverse effects
Not available.

13. Disposal considerations
Disposal instructions
Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information
DOT
Not regulated as a dangerous good.

IATA
Not regulated as dangerous goods.
MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations
One or more components are not listed on TSCA.

- TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
  Not regulated.
- CERCLA Hazardous Substance List (40 CFR 302.4)
  Not listed.
- SARA 304 Emergency release notification
  Not regulated.
- US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
  Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

<table>
<thead>
<tr>
<th>Hazard categories</th>
<th>Immediate Hazard</th>
<th>Delayed Hazard</th>
<th>Fire Hazard</th>
<th>Pressure Hazard</th>
<th>Reactivity Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not listed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- SARA 302 Extremely hazardous substance
  Not listed.
- SARA 311/312 Hazardous chemical
  No
- SARA 313 (TRI reporting)
  Not regulated.

Other federal regulations
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations
US. Massachusetts RTK - Substance List
CALCIUM HYDROXIDE (CAS 1305-62-0)
Not regulated.

US. New Jersey Worker and Community Right-to-Know Act
Not regulated.

US. Pennsylvania RTK - Hazardous Substances
CALCIUM HYDROXIDE (CAS 1305-62-0)
Not regulated.

US. Rhode Island RTK
Not regulated.

US. California Proposition 65
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>Country(s) or region</td>
<td>Inventory name</td>
<td>On inventory (yes/no)*</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

<table>
<thead>
<tr>
<th>Issue date</th>
<th>04-28-2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date</td>
<td>04-28-2014</td>
</tr>
<tr>
<td>Version #</td>
<td>05</td>
</tr>
</tbody>
</table>

Further information

HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings

- Health: 1
- Flammability: 1
- Physical hazard: 0

NFPA ratings

- Health: 1
- Flammability: 1
- Instability: 0

References

GSK Hazard Determination

Disclaimer

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Revision Information

- Composition / Information on Ingredients: Undisclosed Ingredient Statement
- Physical & Chemical Properties: Multiple Properties
- Transport Information: Agency Name, Packaging Type, and Transport Mode Selection
- GHS: Classification