

## Safety Data Sheet acc. to OSHA HCS

Printing date 10/31/2020

Revision date 10/31/2020

### 1 Identification

- **Product identifier**
- **Trade name: Coagulation Factor IX (human, recombinant)**
- **Synonym** Christmas Factor; Coagulation Factor 9; FIX; Plasma Thromboplastin Component; PTC
- **Article number:** 31838
- **Application of the substance / the mixture** For research use only, not for human or veterinary use.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Cayman Chemical Co.  
1180 E. Ellsworth Rd.  
Ann Arbor, MI 48108  
USA
- **Information department:** Product safety department
- **Emergency telephone number:**  
During normal opening times: +1 (734) 971-3335  
US/CANADA: 800-424-9300  
Outside US/CANADA: 703-741-5970

### 2 Hazard(s) identification

- **Classification of the substance or mixture**  
The product is not classified, according to the Globally Harmonized System (GHS).

- **Label elements**
- **GHS label elements** None
- **Hazard pictograms** None
- **Signal word** None
- **Hazard statements** None
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	1	Health = 1
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 7647-14-5 RTECS: VZ4725000	Sodium chloride	73.64%
CAS: 7447-40-7 RTECS: TS8050000	Potassium chloride	1.85%

- **Other ingredients**

CAS: 10028-24-7	Sodium phosphate dibasic dihydrate	13.06%
	Coagulation Factor IX (human, recombinant)	9.2%
CAS: 7778-77-0 RTECS: TC6615500	Potassium phosphate, Monobasic	2.25%

### 4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**  
May cause anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude (weakness, exhaustion), liver damage, narcosis, reproductive effects, teratogenic effects.  
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Use fire fighting measures that suit the environment.  
A solid water stream may be inefficient.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

**Protective Action Criteria for Chemicals**
**PAC-1:**

7778-77-0	Potassium phosphate, Monobasic	9.6 mg/m <sup>3</sup>
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**PAC-2:**

7778-77-0	Potassium phosphate, Monobasic	110 mg/m <sup>3</sup>
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**PAC-3:**

7778-77-0	Potassium phosphate, Monobasic	630 mg/m <sup>3</sup>
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## 7 Handling and storage

**Handling:**

- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.

**Conditions for safe storage, including any incompatibilities**

Keep container tightly closed.  
Store in accordance with information listed on the product insert.

**Storage:**

- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

**Control parameters**
**Components with limit values that require monitoring at the workplace:**

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

At this time, the other constituents have no known exposure limits.

**7647-14-5 Sodium chloride**

PEL	Long-term value: 10 ppm
TLV	Long-term value: 10 mg/m <sup>3</sup> , 10 ppm

**7447-40-7 Potassium chloride**

PEL	Short-term value: 757 mg/m <sup>3</sup> , 250 ppm Long-term value: 606 mg/m <sup>3</sup> , 10 ppm
TLV	Short-term value: 757 mg/m <sup>3</sup> , 250 ppm Long-term value: 606 mg/m <sup>3</sup> , 10 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.

**Exposure controls**
**Personal protective equipment:**
**General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed.

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- **Breathing equipment:** Not required.
- **Protection of hands:**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

## 9 Physical and chemical properties

### · Information on basic physical and chemical properties

#### · General Information

#### · Appearance:

Form:

Solid

Color:

According to product specification

#### · Odor:

Characteristic

#### · Odor threshold:

Not determined.

#### · Formulation

Lyophilized from sterile PBS, pH 7.4

#### · pH-value at 20 °C (68 °F):

7.4

#### · Change in condition

Melting point/Melting range:

Undetermined.

Boiling point/Boiling range:

Undetermined.

#### · Flash point:

Not applicable.

#### · Flammability (solid, gaseous):

Not determined.

#### · Decomposition temperature:

Not determined.

#### · Auto igniting:

Product is not selfigniting.

#### · Danger of explosion:

Product does not present an explosion hazard.

#### · Explosion limits:

Lower:

Not determined.

Upper:

Not determined.

#### · Vapor pressure:

Not applicable.

#### · Density:

Not determined.

#### · Relative density

Not determined.

#### · Vapor density

Not applicable.

#### · Evaporation rate

Not applicable.

#### · Solubility in / Miscibility with

Water:

Soluble.

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- |   |  |
|---|--|
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| · <b>Viscosity:</b>                               |  |
| <b>Dynamic:</b>                                   | Not applicable.                            |
| <b>Kinematic:</b>                                 | Not applicable.                            |
| · <b>Solvent content:</b>                         |  |
| <b>VOC content:</b>                               | 0.00 %                                     |
| <b>Solids content:</b>                            | 99.5 %                                     |
| · <b>Other information</b>                        | No further relevant information available. |

## 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

### ATE (Acute Toxicity Estimate)

Oral	LD50	3,959 mg/kg (rat)
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### 7647-14-5 Sodium chloride

Oral	LDLO	1,000 mg/kg (man)
	TDLO	650 ml/kg (man)
	LD50	4,000 mg/kg (mouse) 3,000 mg/kg (rat)
Inhalative	LD50	4 g/kg (mouse)
	LC50	320 mg/m <sup>3</sup> (mouse)
	TCLO	0.63 mg/m <sup>3</sup> (hmn)
	LCLO	29,300 mg/m <sup>3</sup> /7h (mouse)
Irritation of skin	Irritation	500 mg/24h (rabbit)
Irritation of eyes	Irritation	100 mg/24h (rabbit)
	Intraperitoneal LD50	2,602 mg/kg (mouse)
	Subcutaneous LD50	31.6 mg/kg (rat)
	Intravenous LD50	59.5 mg/kg (rat)
	Data	15 mg/3D (hmn)
	Subcutaneous LD50	3 g/kg (mouse)

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## 7447-40-7 Potassium chloride

Oral	LDLO	20 mg/kg (man)
	TDLO	60 ml/kg (wmn)
	LD50	2,600 mg/kg (rat)
Irritation of eyes	Irritation	500 mg/24h (rabbit)

- **Primary irritant effect:**

- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

## 12 Ecological information

- **Toxicity**

- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability:** No further relevant information available.

- **Behavior in environmental systems:**

- **Bioaccumulative potential:** No further relevant information available.
- **Mobility in soil:** No further relevant information available.

- **Additional ecological information:**

- **General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects:** No further relevant information available.

## 13 Disposal considerations

- **Waste treatment methods**

- **Recommendation:** Smaller quantities can be disposed of with household waste.

- **Uncleaned packagings:**

- **Recommendation:** Disposal must be made according to official regulations.

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· Recommended cleansing agent: Water, if necessary with cleansing agents.

## 14 Transport information

- UN-Number
- DOT, IMDG, IATA not regulated
- UN proper shipping name
- DOT, IMDG, IATA not regulated
- Transport hazard class(es)
- DOT, ADN, IMDG, IATA
- Class not regulated
- Packing group
- DOT, IMDG, IATA not regulated
- Environmental hazards: Not applicable.
- Special precautions for user Not applicable.
- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.
- UN "Model Regulation": not regulated

## 15 Regulatory information

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

### · Section 355 (extremely hazardous substances):

None of the ingredients is listed.

### · Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

### · TSCA (Toxic Substances Control Act):

7647-14-5	Sodium chloride	ACTIVE
7778-77-0	Potassium phosphate, Monobasic	ACTIVE
7447-40-7	Potassium chloride	ACTIVE

### · Hazardous Air Pollutants

None of the ingredients is listed.

### · Proposition 65

#### · Chemicals known to cause cancer:

None of the ingredients is listed.

#### · Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

#### · Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

#### · Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

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- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Environment protection department.

- **Contact:** -

- **Date of preparation / last revision** 10/31/2020 / -

- **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety &amp; Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

- **\* Data compared to the previous version altered.**