

**Product Name:**  
**Issued:**

**Creon**  
**May-18-2018**



## **SAFETY DATA SHEET**

### **Section 1. Identification of the substance/mixture and of the company/undertaking**

#### **1.1 Product Identifier**

**Product Name:** Creon

**Synonyms:** Creon (pancrelipase) Delayed Release Capsules; Creon capsules; Pancreatin capsules; Pancrelipase capsules; Creon Forte capsules; Creon Kapseln; Pancrin Kapseln; Kreon

**Trade name:** Creon; Kreon; Pancrin

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

**Recommended use:** Pharmaceuticals

#### **1.3 Details of the supplier of the safety data sheet**

**Supplier:** Abbott Products Operations AG  
Hegenheimermattweg 127  
4123 Allschwil  
Switzerland

**Manufacturer European:** Abbott Laboratories GmbH  
Justus-Von-Liebig-Strasse 33  
31535 Neustadt  
Germany

**E-mail Address:** Abbott.SDS@abbott.com

#### **1.4 Emergency telephone number**

**Emergency Telephone:** CHEMTREC: 1(800) 424-9300 (in USA and Canada)  
or +1-703-527-3887 (international)

### **Section 2. Hazards identification**

#### **2.1 Classification of the substance or mixture**

**Regulation (EC) No 1272/2008**

<b>Skin corrosion/irritation</b>	Category 2
<b>Serious eye damage/eye irritation</b>	Category 2
<b>Respiratory sensitization</b>	Category 1
<b>Skin sensitization</b>	Category 1
<b>None</b>	

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**Classification according to EU Directives 67/548/EEC or 1999/45/EC**

## 2.2 Label elements



**Signal Word:** Danger

**Hazard Statements:**  
H315 - Causes skin irritation  
H317 - May cause an allergic skin reaction  
H319 - Causes serious eye irritation  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

**Precautionary Statements**  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water  
P285 - In case of inadequate ventilation wear respiratory protection  
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing

## 2.3 Other hazards

Not determined

## **Section 3. Composition/information on ingredients**

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Pancreatin 8049-47-6	60.1	Present		Resp. Sens. 1 (H334) Skin Sens. 1 (H317) Skin Irrit 2 (H315) Eye Irrit 2 (H319)	No data available
Hypromellose phthalate 9050-31-1	22.6	NA		Not Hazardous*	No data available
Polyethylene Glycols 25322-68-3	15	NA		Not Hazardous*	No data available
Triethyl Citrate 77-93-0	1.3	Present		Not Hazardous*	No data available
Poly(dimethylsiloxane) 9016-00-6	0.5	NA		Aquatic Chronic 4 (H413)	No data available
Cetyl alcohol 36653-82-4	0.5	Present		Not Hazardous*	No data available

Not Hazardous\* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

**For the full text of the R-phrases mentioned in this Section, see Section 16**

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**For the full text of the H-Statements mentioned in this Section, see Section 16**

## **Section 4. First aid measures**

### **4.1 Description of first aid measures**

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Protection of First-aiders:** Use personal protective equipment

### **4.2 Most important symptoms and effects, both acute and delayed**

**Signs and Symptoms:** Clinical data suggests the following: gastrointestinal upset. Allergic reactions, respiratory irritation, eye irritation, skin irritation, breathing difficulty,

**Medical Conditions Aggravated by Exposure:** None known from occupational exposure.

### **4.3 Indication of any immediate medical attention and special treatment needed**

**Notes To Physician:** Treat symptomatically

## **Section 5. Firefighting measures**

### **5.1 Extinguishing Media**

**Suitable Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire

**Unsuitable Extinguishing Media:** Not determined

### **5.2 Special hazards arising from the substance or mixture**

**Special Exposure Hazards:** This material is capable of forming explosive dust clouds in air, therefore, measures must be taken to avoid ignition. This material is particularly sensitive to ignition by electrostatic discharge.

**Explosivity:** dust explosion hazard.

### **5.3 Advice for firefighters**

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus and full protective gear

## **Section 6. Accidental release measures**

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### **6.1. Personal precautions, protective equipment and emergency procedures**

**Personal Precautions:** Avoid contact with skin, eyes and clothing. Use personal protective equipment. Ensure adequate ventilation. Avoid dust formation. All equipment used when handling the product must be grounded.

### **6.2. Environmental precautions**

**Environmental Precautions:** Contain material and prevent release to waterways or soil.

### **6.3. Methods and material for containment and cleaning up**

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal.

### **6.4. Reference to other sections**

Refer to Sections 8, 12, and 13 for further information.

## **Section 7. Handling and storage**

### **7.1. Precautions for safe handling**

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Wear personal protective equipment. Take precautionary measures against static discharges. Fine dust dispersed in air may ignite. Avoid dust formation.

### **7.2. Conditions for safe storage, including any incompatibilities**

Store according to label instructions.

### **7.3. Specific end use(s)**

**Recommended use:** Pharmaceuticals

## **Section 8. Exposure controls/personal protection**

### **8.1. Control parameters**

#### **Exposure limits:**

Chemical Name	Employee Exposure Limit	Skin Notation
Pancreatin 8049-47-6	160 mcg/m <sup>3</sup>	None
Hypromellose phthalate 9050-31-1	Not Applicable	None
Polyethylene Glycols 25322-68-3	Not Applicable	None
Triethyl Citrate 77-93-0	Not Applicable	None
Poly(dimethylsiloxane) 9016-00-6	Not Applicable	None
Cetyl alcohol 36653-82-4	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Hypromellose phthalate 9050-31-1	10 mg/m <sup>3</sup> total dust 3 mg/m <sup>3</sup> respirable dust				

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Polyethylene Glycols 25322-68-3			1000 mg/m <sup>3</sup> TWA 8000 mg/m <sup>3</sup> Peak		
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Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Polyethylene Glycols 25322-68-3			1000 mg/m <sup>3</sup> (TWA)	

## **8.2. Exposure controls**

<b>Engineering Controls:</b>	No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.
<b>Respiratory Protection:</b>	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.
<b>Eyes:</b>	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
<b>Gloves:</b>	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.
<b>Other PPE Data:</b>	Wear appropriate body coverings if contact may occur.
<b>Environmental Exposure Controls:</b>	Not determined

## **Section 9. Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

<b>Appearance:</b>	Capsule
<b>Odor:</b>	Odorless.
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	Not determined.
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	Not determined.
<b>Melting/Freezing Point (°C):</b>	Not determined
<b>Flash Point (°C):</b>	Not determined.
<b>Evaporation Rate at 20°C:</b>	Not determined.
<b>Flammability (Solid):</b>	Not determined.
<b>Lower Explosive Limit:</b>	Not determined.
<b>Upper Explosive Limit:</b>	Not determined.
<b>Vapor Pressure (mm Hg):</b>	Not determined.
<b>Vapor Density (Air = 1):</b>	Not determined.
<b>Specific Gravity:</b>	Not determined.
<b>Solubility(ies):</b>	Not determined.
<b>Partition coefficient:</b>	Not determined.
<b>n-octanol/water</b>	
<b>Autoignition Temp. (°C):</b>	Not determined.
<b>Decomposition temperature (°C):</b>	Not determined.
<b>Explosion Severity:</b>	Not determined.
<b>Oxidizer Properties:</b>	Not determined.

### **9.2. Other information**

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Not determined  
**Explosivity:** dust explosion hazard.

## Section 10. Stability and reactivity

### 10.1. Reactivity

Not determined

### 10.2. Chemical stability

Stable under normal conditions

### 10.3. Possibility of hazardous reactions

**Hazardous reactions:** Not determined.

### 10.4. Conditions to avoid

Protect from moisture

### 10.5 Incompatible materials

Not determined

### 10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NOx)

## Section 11. Toxicological information

### 11.1. Information on toxicological effects

#### Routes of Exposure:

**Oral:** Clinical Route  
**Dermal:** Unlikely  
**Inhalation:** Unlikely

**Acute Toxicity - Oral:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Pancreatin 8049-47-6	LD50 >	15,000 15,000 15,000	mg/kg	Rats Mice Dogs
Hypromellose phthalate 9050-31-1	LD50 >	15000	mg/kg	Rats
Polyethylene Glycols 25322-68-3	LD50 >	47,000 28,000 33,750	mg/kg	Mice Rats Rats
Triethyl Citrate 77-93-0	LD50 =	3500 5900	mg/kg	Cats Rats

**Acute Toxicity - Dermal:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Polyethylene Glycols 25322-68-3	LD50 >	20,000	mg/kg	Rabbits
Triethyl Citrate 77-93-0	LD50 >	5000	mg/kg	Rabbits

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**Acute Toxicity - Inhalation:** Not determined.

**Other Toxicology Data:** Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Pancreatin 8049-47-6	LD50 (ip) =	2,550	mg/kg	Rats	
		2,100		Mice	
	LD 50 (sc) >	5,000		Rats	
	LD50 (sc) =	3,780		Mice	
Triethyl Citrate 77-93-0	LD50 (ip) =	4000	mg/kg	Rats	None.
Poly(dimethylsiloxane) 9016-00-6	LD 50 (sc) >	410	mg/kg	Dogs	None.
	LD 50 (ip) >	410	mg/kg		

**Corrosivity:** Not determined.

**Dermal Irritation:** The active ingredient is a skin irritant.

**Eye Irritation:** The active ingredient is an eye irritant.

**Sensitization:** Active Ingredient : Reported to be sensitizer in humans.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** Not determined.

**Reproductive Effects:** Not determined.

**Carcinogenicity:** Not determined.

**Mutagenicity:** Not determined.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Polyethylene Glycols 25322-68-3	No Data.	Negative	No Data.	No Data.

**Aspiration hazard:** Not determined

**Notes:**

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

## Section 12. Ecological information

### 12.1. Toxicity

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Pancreatin 8049-47-6	50-70	422	Brachydanio rerio	48 Hours

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#### **12.2. Persistence and degradability**

Not determined.

#### **12.3. Bioaccumulative potential**

Not determined

#### **12.4. Mobility in soil**

Not determined.

#### **12.5. Results of PBT or vPvB assessment**

Chemical safety report is not required for this substance/product.

#### **12.6. Other adverse effects**

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

#### **Notes:**

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

### **Section 13. Disposal considerations**

#### **13.1 Waste treatment methods**

**Waste Disposal Methods:** Disposal should be made in accordance with country, federal, state and local regulations.

### **Section 14. Transport information**

#### **ADR, DOT, ICAO/IATA, IMDG/IMO**

**Status:** Not regulated

**14.1. UN Number:** Not applicable  
**14.2. Proper shipping name:** Not applicable  
**14.3. Hazard class:** Not applicable  
**14.4. Packing group:** Not applicable  
**14.5. Environmental hazard:** Not applicable  
**14.6. Special Provisions:** Not applicable  
**14.7. Transport in bulk** Not applicable  
**according to Annex II of**  
**MARPOL 73/78 and the IBC**  
**Code:**

### **Section 15. Regulatory Information**



**Product Name:** Creon  
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### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Pancreatin 8049-47-6	Present	X	-	Not listed.	X
Hypromellose phthalate 9050-31-1	-	X	-	X	X
Polyethylene Glycols 25322-68-3	-	X	X	Not listed.	X
Triethyl Citrate 77-93-0	Present	X	X	Not listed.	X
Poly(dimethylsiloxane) 9016-00-6	-	-	X	Not listed.	X
Cetyl alcohol 36653-82-4	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Pancreatin 8049-47-6	-	-	X	X	Present	HSR004052
Hypromellose phthalate 9050-31-1	Present	-	X	X	Present	
Polyethylene Glycols 25322-68-3	Present	-	X	X	Present	
Triethyl Citrate 77-93-0	Present	-	X	X	Present	
Poly(dimethylsiloxane) 9016-00-6	Present	-	X	X	Present	
Cetyl alcohol 36653-82-4	Present	-	X	X	Present	HSR003844

#### **Legend**

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**ISHL** - Japan Industrial Safety and Health Law

**IECSC** - China Inventory of Existing Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

#### **Carcinogenicity Rating:**

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Pancreatin	50-70	Not Listed	Not Listed	Not Listed
Hypromellose phthalate	10-30	Not Listed	Not Listed	Not Listed
Polyethylene Glycols	10-20	Not Listed	Not Listed	Not Listed
Triethyl Citrate	1-5	Not Listed	Not Listed	Not Listed
Poly(dimethylsiloxane)	0.1-1	Not Listed	Not Listed	Not Listed
Cetyl alcohol	0.1-1	Not Listed	Not Listed	Not Listed

#### **SARA 313 Information**

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Pancreatin	50-70	No	Not Applicable	Not applicable
Hypromellose phthalate	10-30	No	Not Applicable	Not applicable
Polyethylene Glycols	10-20	No	Not Applicable	Not applicable
Triethyl Citrate	1-5	No	Not Applicable	Not applicable
Poly(dimethylsiloxane)	0.1-1	No	Not Applicable	Not applicable
Cetyl alcohol	0.1-1	No	Not Applicable	Not applicable

**Immediate Health:** Yes

**Delayed Health:** No

**Fire:** No

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**Sudden Pressure:** No  
**Reactivity:** No  
**RCRA Status:** Not determined.  
**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.  
**WHMIS Hazard Class:** Not determined.  
**NFPA Rating:**  
Health: 1  
Fire: 1  
Reactivity: 0

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

**15.2. Chemical safety assessment**

Chemical safety assessment has not been conducted on the substance/product.

<b>Section 16. Other information</b>
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**Full text of H-Statements referred to under sections 2 and 3**

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H317 - May cause an allergic skin reaction  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H413 - May cause long lasting harmful effects to aquatic life

**Document Authored By:** Global Occupational Toxicology

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**Disclaimer:**

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