

Product Name: Creon
Issued: Apr-29-2015



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 Kapslen; Pancrin Kapseln; Kreon; Creon 36,000; Creon 3000; Creon 6000; Creon 12000; Creon 24000

Trade name: Creon; Kreon; Pancrin

List Number: 1024; 1025; 1026; 3823; 1203; 3016

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: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-847-932-7900

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.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

Respiratory sensitization Category 1

Skin sensitization Category 1

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

Indication of danger: Xn - Harmful

Risk Phrases: R42 - May cause sensitization by inhalation

R43 - May cause sensitization by skin contact

2.2 Label elements

Product Name:
Issued:

Creon
Apr-29-2015



Signal Word: Danger

Hazard Statements: H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary Statements P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
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
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician

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	50-70	Present	Xn; R42, R43	Resp. Sens. 1 (H334) Skin Sens. 1 (H317)	No data available
Hypromellose phthalate 9050-31-1	10-30	NA		Not Hazardous*	No data available
Polyethylene Glycols 25322-68-3	10-20	NA	Xi, R37	STOT SE 3 (H335)	No data available
Triethyl Citrate 77-93-0	1-5	Present		Not Hazardous*	No data available
Polydimethylsiloxane 9016-00-6	0.1-1	NA	R53	Aquatic Chronic 4 (H413)	No data available
Cetyl alcohol 36653-82-4	0.1-1	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
For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

Product Name: Creon
Issued: Apr-29-2015

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.

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: Not determined

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

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8.

6.2. Environmental precautions

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

Product Name: Creon
Issued: Apr-29-2015

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

Handle in accordance with good industrial hygiene and safety practice.

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 ³	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
Polydimethylsiloxane 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 ³ total dust 3 mg/m ³ respirable dust				
Polyethylene Glycols 25322-68-3			8000 mg/m ³ Peak		

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Polyethylene Glycols 25322-68-3			1000 ppm (TWA)	

8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.

Respiratory Protection: 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.

Product Name: Creon
Issued: Apr-29-2015

Eyes: Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

Gloves: Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

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

9.2. Other information

Not determined

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Product Name: Creon
Issued: Apr-29-2015

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	mg/kg	Rats
		15,000		Mice
		15,000		Dogs
Hypromellose phthalate 9050-31-1	LD50 >	15000	mg/kg	Rats
Polyethylene Glycols 25322-68-3	LD50 =	47,000	mg/kg	Mice
		28,000		Rats
		33,750		Rats
Triethyl Citrate 77-93-0	LD50 =	3500	mg/kg	Cats
		5900		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

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.
Polydimethylsiloxane 9016-00-6	LD 50 (sc) >	410	mg/kg	Dogs	None.
	LD 50 (ip) >	410	mg/kg		

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Product Name: Creon
Issued: Apr-29-2015

Eye Irritation: Not determined.

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

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Not determined.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Polyethylene Glycols 25322-68-3	Lungs	Rats	567 mg/m ³		Inhalation	2 weeks

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

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.

Product Name: Creon
Issued: Apr-29-2015

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

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
Polydimethylsiloxane 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	

Product Name:
Issued:

Creon
Apr-29-2015

Polydimethylsiloxane 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
Polydimethylsiloxane	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
Polydimethylsiloxane	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
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

Product Name: Creon
Issued: Apr-29-2015

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

Section 16. Other information

Risk Phrases:

R42 - May cause sensitization by inhalation

R43 - May cause sensitization by skin contact

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

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