

Product Name: Sormodren Tablets
Issued: Feb-15-2012



SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Sormodren Tablets
Synonyms: Sormodren Tablets, 4 mg; Bornaprine Hydrochloride 4 mg Tablets; Sormodren; Sormodren Tabletten
List Number: N305

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

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

Serious eye damage/eye irritation Category 2

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

Indication of danger: Xi - Irritant

Risk Phrases: R36 - Irritating to eyes

2.2 Label elements



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Section 2. Hazards identification

Signal Word: Warning

Hazard Statements: H319 - Causes serious eye irritation

Precautionary Statements: P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
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

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.
Starch 9005-25-8	40-60	232-679-6		Not classified	No data available
Lactose monohydrate 10039-26-6	5-20	NA		Not classified	No data available
Cellulose Microcrystalline 9004-34-6	5-20	232-674-9		Not classified	No data available
Calcium hydrogen phosphate, dihydrate 7789-77-7	5-20	NA		Not classified	No data available
Copovidone 25086-89-9	5-20	NA		Not classified	No data available
Talc, Nonasbestos Containing 14807-96-6	1-10	238-877-9		Not classified	No data available
Bornaprine 20448-86-6	1-2.9	NA	Xn, R20/22 R41	Eye Dam. 1 (H318) Acute Tox. 4 (H302) Acute Tox. 4 (H332)	No data available

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

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.

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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: None known from occupational exposure. Available information support the following: agitation, confusion, hallucinations, insomnia, nervousness, restlessness, dizziness, headaches, memory lapse, photophobia, constipation, dry mouth, dyspepsia, nausea, fatigue, urinary retention, vomiting.

Medical Conditions Aggravated by Exposure: Hypersensitivity to the material and/or similar materials.

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.

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.

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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	Abbott EEL	Skin Notation
Starch 9005-25-8	Not Applicable	None
Lactose monohydrate 10039-26-6	Not Applicable	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Calcium hydrogen phosphate, dihydrate 7789-77-7	Not Applicable	None
Copovidone 25086-89-9	Not Applicable	None
Talc, Nonasbestos Containing 14807-96-6	Not Applicable	None
Bornaprine 20448-86-6	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Starch 9005-25-8	10 mg/m ³ total dust for Starch			10 mg/m ³ (TWA) 4 mg/m ³ (TWA) 10 mg/m ³ (TWA)	
Cellulose Microcrystalline 9004-34-6	10 mg/m ³ total dust	TWA: 10 mg/m ³		20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	
Talc, Nonasbestos Containing 14807-96-6	2 mg/m ³ , respirable dust			10 mg/m ³ (TWA) 0.8 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Starch 9005-25-8		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 30 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
Cellulose Microcrystalline 9004-34-6		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	20 mg/m ³ (STEL) 12 mg/m ³ (STEL) 20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
Talc, Nonasbestos Containing 14807-96-6	0.25 mg/m ³ (TWA)	2 mg/m ³ (TWA)	2 mg/m ³ (TWA)	3 mg/m ³ (STEL) 1 mg/m ³ (TWA)

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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.

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: Off-White Oval tablet

Odor: Not determined.

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: n-octanol/water Not determined.

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

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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

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Yes
Inhalation: Unlikely

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

Chemical Name	Acute Test	Value	Units	Species
Lactose monohydrate 10039-26-6	LD50 >	10000	mg/kg, for a similar material	Rats
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Bornaprine 20448-86-6	LD50 =	687-705	mg/kg	Rats

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

Chemical Name	Acute Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LD50 >	2000	mg/kg	Rabbits

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

Chemical Name	Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LC 50 >	5800	mg/m ³ , 4 hour	Rats
Bornaprine 20448-86-6	LC50 =	1.03	mg/L, 4 hour	Rats

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

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Chemical Name	Test Type	Value	Units	Species	Comments
Bornaprine 20448-86-6	LD50 (iv) = LD50 (sc) =	26 112	mg/kg	Mice	None.

Corrosivity: Not determined.
Dermal Irritation: Not determined.
Eye Irritation: Active Ingredient : Produced severe eye irritation in animals.
Sensitization: Not determined.
Toxicokinetics/Metabolism: Not determined.
Target Organ Effects: Not determined.
Reproductive Effects: Not determined.
Carcinogenicity: Not determined.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Talc, Nonasbestos Containing 14807-96-6	Lungs	Rats	18	Inhalation	mg/m ³ , 6 hours	2 years

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Lactose monohydrate 10039-26-6	No Data.	Negative	No Data.	Negative
Bornaprine 20448-86-6	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

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

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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 according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

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
Starch 9005-25-8	232-679-6	X	X	Not listed.	X
Lactose monohydrate 10039-26-6	-	-	-	Not listed.	-
Cellulose Microcrystalline 9004-34-6	232-674-9	X	X	Not listed.	X
Calcium hydrogen phosphate, dihydrate 7789-77-7	-	-	X	Not listed.	X
Copovidone 25086-89-9	-	X	X	Not listed.	X
Talc, Nonasbestos Containing 14807-96-6	238-877-9	X	X	Not listed.	X

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Bornaprine 20448-86-6	-	-	-	Not listed.	-
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Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Starch 9005-25-8	(8)-98	-	X	X	KE-32128	
Lactose monohydrate 10039-26-6	-	-	X	X	-	
Cellulose Microcrystalline 9004-34-6	(8)-568	-	X	X	KE-05339	
Calcium hydrogen phosphate, dihydrate 7789-77-7	(1)-183	-	X	X	-	
Copovidone 25086-89-9	(6)-326	-	X	X	KE-00043	
Talc, Nonasbestos Containing 14807-96-6	(1)-468	-	X	X	KE-32773	
Bornaprine 20448-86-6	-	-	-	-	-	

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:
Starch	40-60	Not Listed	Not Listed	Not Listed
Lactose monohydrate	5-20	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	5-20	Not Listed	Not Listed	Not Listed
Calcium hydrogen phosphate, dihydrate	5-20	Not Listed	Not Listed	Not Listed
Copovidone	5-20	Not Listed	Not Listed	Not Listed
Talc, Nonasbestos Containing	1-10	Not Listed	Not Listed	Not Listed
Bornaprine	1-2.9	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):
Starch	40-60	No	Not Applicable	Not applicable
Lactose monohydrate	5-20	No	Not Applicable	Not applicable
Cellulose Microcrystalline	5-20	No	Not Applicable	Not applicable
Calcium hydrogen phosphate, dihydrate	5-20	No	Not Applicable	Not applicable
Copovidone	5-20	No	Not Applicable	Not applicable
Talc, Nonasbestos Containing	1-10	No	Not Applicable	Not applicable
Bornaprine	1-2.9	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.

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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.

Section 16. Other information

Risk Phrases: R36 - Irritating to eyes

Full text of H-Statements referred to under sections 2 and 3

H318 - Causes serious eye damage, H302 - Harmful if swallowed, H332 - Harmful if inhaled

Document Authored By: Global Occupational Toxicology (D-03QC)

Issued: Feb-15-2012

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