

**Product Name:** Isoptin Granulates  
**Issued:** Apr-16-2015

**abbvie**  
**SAFETY DATA SHEET**

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

**1.1 Product Identifier**

**Product Name:** Isoptin Granulates  
**Synonyms:** Isoptin Granules; Isoptin Granulation; Isoptin Granulates; Verapamil Granulates, Verapamil Granules  
**Drug Code Number:** 14188961

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

**Recommended use:** Industrial use  
Scientific research and development  
Process Intermediate

**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  
**Manufacturer European:** AbbVie Deutschland GmbH & Co. KG50  
Ludwigshafen  
**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**

**Acute oral toxicity** Category 3  
**Skin corrosion/irritation** Category 2  
**Serious eye damage/eye irritation** Category 2  
**Specific target organ systemic toxicity (single exposure)** Category 3  
**Chronic aquatic toxicity** Chronic toxicity 3

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

**Indication of danger:** T - Toxic  
Xi - Irritant

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## 2.2 Label elements



**Signal Word:** Danger

**Hazard Statements:**  
H301 - Toxic if swallowed  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H335 - May cause respiratory irritation  
H412 - Harmful to aquatic life with long lasting effects

**Precautionary Statements**  
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water  
P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing  
P273 - Avoid release to the environment

## 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.
Sodium Alginate 9005-40-7	40-60	NA		Not Hazardous*	No data available
Verapamil Hydrochloride 152-11-4	30-50	Present	T, R25; Xi, R36/37/38; R52, 53	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Acute Tox. 3 (H301) Aquatic Chronic 3 (H412)	No data available
Cellulose Microcrystalline 9004-34-6	5-20	Present		Not Hazardous*	No data available
Kollidon 9003-39-8	5-20	NA		Not Hazardous*	No data available
Water 7732-18-5	1-10	Present		Not Hazardous*	No data available
Magnesium Stearate 557-04-0	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.

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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.

**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.

**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**

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**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.

## **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:** Industrial use  
Scientific research and development  
Process Intermediate

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

### **8.1. Control parameters**

#### **Exposure limits:**

<b>Chemical Name</b>	<b>Employee Exposure Limit</b>	<b>Skin Notation</b>
Sodium Alginate 9005-40-7	Not Applicable	None
Verapamil Hydrochloride 152-11-4	60 mcg/m <sup>3</sup> TWA	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Kollidon 9003-39-8	Not Applicable	None
Water 7732-18-5	Not Applicable	None
Magnesium Stearate 557-04-0	Not Applicable	None

<b>Chemical Name</b>	<b>ACGIH TLV</b>	<b>France</b>	<b>German MAK</b>	<b>Ireland</b>	<b>Italy</b>
Sodium Alginate 9005-40-7	10 mg/m <sup>3</sup> , total dust; 3 mg/m <sup>3</sup> respirable particulate				
Cellulose Microcrystalline 9004-34-6	10 mg/m <sup>3</sup> TWA	TWA: 10 mg/m <sup>3</sup>		20 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)	5.00 mg/m <sup>3</sup> (TWA)
Kollidon 9003-39-8	10 mg/m <sup>3</sup> for nuisance dust; 3 mg/m <sup>3</sup> respirable particulate				

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Magnesium Stearate 557-04-0	10 mg/m <sup>3</sup> total dust			10 mg/m <sup>3</sup> (TWA)	
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Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Cellulose Microcrystalline 9004-34-6		10 mg/m <sup>3</sup> (TWA)	3 mg/m <sup>3</sup> (TWA)	20 mg/m <sup>3</sup> (STEL) 12 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)
Magnesium Stearate 557-04-0		10 mg/m <sup>3</sup> (TWA)		

## 8.2. Exposure controls

<b>Engineering Controls:</b>	Utilize appropriate engineering controls ( i.e. hood, glovebox, or process enclosure) when handling open containers of this compound.
<b>Respiratory Protection:</b>	An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.
<b>Eyes:</b>	Wear eye protection appropriate to handling activities.
<b>Gloves:</b>	Impervious gloves.
<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>	Light brown Granules
<b>Odor:</b>	Not determined.
<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>Viscosity (centipoise):</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

## 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

Not determined.

### 10.5 Incompatible materials

Not determined

### 10.6 Hazardous decomposition products

Not determined

## 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
Sodium Alginate 9005-40-7	LD50 >	5000	mg/kg	Rats
Verapamil Hydrochloride 152-11-4	LD50 =	108 140 163 >400	mg/kg	Rats Guinea Pigs Mice Dogs
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Kollidon 9003-39-8	LD50 = LD50 >	100000 1040 40000	mg/kg	Rats Rabbits Mice

**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.

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Chemical Name	Test	Value	Units	Species	
Cellulose Microcrystalline 9004-34-6	LC 50 >	5800	mg/m³ , 4 hour	Rats	
Magnesium Stearate 557-04-0	LC 50 >	2000	mg/m³ , 1 hour	Rats	
Chemical Name	Test Type	Value	Units	Species	Comments
Verapamil Hydrochloride 152-11-4	LD50 (sc) =	68-107	mg/kg	Mice Rats	None.

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Verapamil Hydrochloride 152-11-4	Eyes	Dogs	60	mg/kg	Oral	12 weeks

**Reproductive Effects:** Not determined.

**Carcinogenicity:** Not determined.

**Mutagenicity:** Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Verapamil Hydrochloride 152-11-4	No Data.	Negative	No Data.	No Data.
Magnesium Stearate 557-04-0	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.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Verapamil Hydrochloride 152-11-4	30-50	> 4.6 < 10	Golden Orfe	96 Hours

### 12.2. Persistence and degradability

Not determined.

Chemical Name	Percent	% Degradation	Duration
Verapamil Hydrochloride 152-11-4	30-50	<20	Unspecified

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### **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**

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

#### **International Inventories**

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Sodium Alginate 9005-40-7	-	-	-	Not listed.	-



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Verapamil Hydrochloride 152-11-4	Present	-	X	Not listed.	-
Cellulose Microcrystalline 9004-34-6	Present	X	X	Not listed.	X
Kollidon 9003-39-8	-	X	X	Not listed.	X
Water 7732-18-5	Present	X	X	Not listed.	X
Magnesium Stearate 557-04-0	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Sodium Alginate 9005-40-7	-	-	-	-	-	
Verapamil Hydrochloride 152-11-4	-	-	-	X	-	HSR007000
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	Present	
Kollidon 9003-39-8	Present	-	X	X	Present	
Water 7732-18-5	-	-	X	X	Present	
Magnesium Stearate 557-04-0	Present	-	X	X	Present	

**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:
Sodium Alginate	40-60	Not Listed	Not Listed	Not Listed
Verapamil Hydrochloride	30-50	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	5-20	Not Listed	Not Listed	Not Listed
Kollidon	5-20	Not Listed	Not Listed	Not Listed
Water	1-10	Not Listed	Not Listed	Not Listed
Magnesium Stearate	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):
Sodium Alginate	40-60	No	Not Applicable	Not applicable
Verapamil Hydrochloride	30-50	No	Not Applicable	Not applicable
Cellulose Microcrystalline	5-20	No	Not Applicable	Not applicable
Kollidon	5-20	No	Not Applicable	Not applicable
Water	1-10	No	Not Applicable	Not applicable
Magnesium Stearate	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.

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**WHMIS Hazard Class:** D1B TOXIC MATERIALS.

**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**

H301 - Toxic if swallowed  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H335 - May cause respiratory irritation  
H412 - Harmful to aquatic life with long lasting effects

**Document Authored By:** Occupational and Environmental Toxicology

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