

Product Name: Rytmonorm 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: Rytmonorm Granulates
Synonyms: Rytmonorm Granules; Rytmonorm Granulation; Rytmonorm Granulates;
Norfenon Granulates; Norfenon Granules
Drug Code Number: 16114967

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 4

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

2.2 Label elements



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Signal Word: Warning

Hazard Statements: H302 - Harmful if swallowed

Precautionary Statements P312 - Call a POISON CENTER or doctor/physician if you feel unwell
P281 - Use personal protective equipment as required
P353 - Rinse skin with water/shower

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.
Propafenone Hydrochloride 34183-22-7	60-80	Present	Xn, R22	Acute Tox. Cat. 4 (H302)	No data available
Cellulose Microcrystalline 9004-34-6	5-20	Present		Not Hazardous*	No data available
Starch 9005-25-8	5-20	Present		Not Hazardous*	No data available
Hydroxypropyl Methylcellulose 9004-65-3	1-10	NA		Not Hazardous*	No data available
Croscarmellose Sodium 9000-11-7	1-10	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.

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.

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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 None known from occupational exposure.

Aggravated by 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.

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

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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:

Chemical Name	Employee Exposure Limit	Skin Notation
Propafenone Hydrochloride 34183-22-7	500 mcg/m ³ TWA	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Starch 9005-25-8	Not Applicable	None
Hydroxypropyl Methylcellulose 9004-65-3	Not Applicable	None
Croscarmellose Sodium 9000-11-7	Not Applicable	None
Water 7732-18-5	Not Applicable	None
Magnesium Stearate 557-04-0	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Cellulose Microcrystalline 9004-34-6	10 mg/m ³ TWA	TWA: 10 mg/m ³		20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	5.00 mg/m ³ (TWA)
Starch 9005-25-8	10 mg/m ³ TWA			10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m ³ total dust; 3 mg/m ³ respirable dust				
Croscarmellose Sodium 9000-11-7	10 mg/m ³ as nuisance dust, 3 mg/m ³ for respirable particulate				
Magnesium Stearate 557-04-0	10 mg/m ³ total dust			10 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
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) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
Starch 9005-25-8		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
Magnesium Stearate 557-04-0		10 mg/m ³ (TWA)		

8.2. Exposure controls

Engineering Controls: Use in a well ventilated area.

Respiratory Protection: An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities.

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Gloves: Impervious gloves.

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:	White Granules
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:	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

Hazardous reactions: Not determined.

10.4. Conditions to avoid

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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
Propafenone Hydrochloride 34183-22-7	LD50 =	341 700	mg/kg	Mice Rats
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats
Croscarmellose Sodium 9000-11-7	LD50 >	5050	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
Croscarmellose Sodium 9000-11-7	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
Croscarmellose Sodium 9000-11-7	LC 50 >	0.13	mg/L , 4 hour	Rats
Magnesium Stearate 557-04-0	LC 50 >	2000	mg/m ³ , 1 hour	Rats

Chemical Name	Test Type	Value	Units	Species	Comments
Propafenone Hydrochloride 34183-22-7	LD50 (sc) =	156 100	mg/kg mg/kg	Rats Mice	None.

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

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

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Propafenone Hydrochloride 34183-22-7	Kidney Liver	Rats	180	mg/kg	Oral	Repeat dose study (ies).

Reproductive Effects: Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration	Propafenone Hydrochloride 34183-22-7
Rabbits Rats	130	mg/kg	Oral	During Gestation		

Carcinogenicity: Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Propafenone Hydrochloride 34183-22-7	None	Rats Mice	> 270	Oral	mg/kg	Lifetime

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Propafenone Hydrochloride 34183-22-7	Negative	Negative	No Data.	Negative
Croscarmellose Sodium 9000-11-7	No Data.	Negative	No Data.	Negative
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.

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.

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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
Propafenone Hydrochloride 34183-22-7	Present	-	-	Not listed.	-
Cellulose Microcrystalline 9004-34-6	Present	X	X	Not listed.	X
Starch 9005-25-8	Present	X	X	Not listed.	X
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed.	X
Croscarmellose Sodium 9000-11-7	-	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
Propafenone Hydrochloride 34183-22-7	-	Present	-	-	-	
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	Present	

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Starch 9005-25-8	Present	-	X	X	Present	
Hydroxypropyl Methylcellulose 9004-65-3	Present	-	X	X	Present	
Croscarmellose Sodium 9000-11-7	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:
Propafenone Hydrochloride	60-80	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	5-20	Not Listed	Not Listed	Not Listed
Starch	5-20	Not Listed	Not Listed	Not Listed
Hydroxypropyl Methylcellulose	1-10	Not Listed	Not Listed	Not Listed
Croscarmellose Sodium	1-10	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):
Propafenone Hydrochloride	60-80	No	Not Applicable	Not applicable
Cellulose Microcrystalline	5-20	No	Not Applicable	Not applicable
Starch	5-20	No	Not Applicable	Not applicable
Hydroxypropyl Methylcellulose	1-10	No	Not Applicable	Not applicable
Croscarmellose Sodium	1-10	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.

WHMIS Hazard Class: Not determined.

NFPA Rating:

Health: 1

Fire: 1

Reactivity: 0

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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

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

H302 - Harmful if swallowed

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Disclaimer:

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