SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Niacin uncoated tablets

Synonyms: Niaspan Tablets, uncoated; Niacin ER cores; Niacin non-debossed core uncoated tablet; Niacin ER, uncoated tablets; Niaspan cores; Niacin ER; Niacin ER tablets

Reach Registration Number 3001; 3003; 3004

List Number: 10479; 10482; 10486; 10550; 10526; 10525; 10551; 10509; 10507; 3445; 3446

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
1-800-255-5162
+1-847-937-7433

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
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

Section 2. Hazards identification

Signal Word: Warning

Hazard Statements: H319 - Causes serious eye irritation

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.
Nicotinic Acid 59-67-6	60-90	Present	Xi, R36	Eye Irrit. 2 (H319)	No data available
Hydroxypropyl Methylcellulose 9004-65-3	10-30	NA		Not Hazardous*	No data available
Kollidon 9003-39-8	1-10	NA		Not Hazardous*	No data available
Stearic Acid 57-11-4	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

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: Available information support the following: flushing, fast heart rate, Clinical data suggests the following: gastrointestinal upset, pruritus, hypotension, dizziness, headaches, blurred vision, hyperuricemia, hyperglycemia (high blood sugar), glycosuria.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: kidney, liver, nervous system, gastrointestinal system.

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

Explosivity: Fine dust clouds may form explosive mixtures with air.

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

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Apply measures to prevent dust explosions..

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
Nicotinic Acid 59-67-6	1000 mcg/m^3	None
Hydroxypropyl Methylcellulose 9004-65-3	Not Applicable	None
Kollidon 9003-39-8	Not Applicable	None
Stearic Acid 57-11-4	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Nicotinic Acid 59-67-6	3 mg/m^3 for respirable particles and 10 mg/m^3 for inhalable particles				
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m^3 total dust; 3 mg/m^3 respirable dust				
Kollidon 9003-39-8	10 mg/m^3 for nuisance dust; 3 mg/m^3 respirable particulate				
Stearic Acid 57-11-4	10 mg/m^3 for nuisance dust; 3 mg/m^3 respirable particulate				

8.2. Exposure controls

Engineering Controls: When handling bulk formulation, use in a well-ventilated area.

Respiratory Protection: 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:	Wear eye protection appropriate to exposures when handling the product formulation.
Gloves:	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:	White to off-white Tablet
Odor:	Faint odor.
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):	Soluble in: water.
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

Explosivity:	Fine dust clouds may form explosive mixtures with air.
Maximum Pressure Rise (bar):	7.8
Max. rate of pressure rise (bar/sec):	944
Kst Value (bar.m/s):	256
Min. Ignition Energy-Cloud (mJ):	3-5
Min. Ignit. Temp. Dust Cloud (°C):	420-440
Min. Explosive Conc. (g/m^3):	40-50
Min. Ignition Temp.-Layer (°C):	> 400

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

Dust formation

10.5 Incompatible materials

Not determined

10.6 Hazardous decompostion products

Not determined.

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Yes
Inhalation: Not determined.

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

Chemical Name	Acute Test	Value	Units	Species
Nicotinic Acid 59-67-6	LD50 = 	3720 4550 7000	mg/kg	Mice Rabbits Rats
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats
Kollidon 9003-39-8	LD50 = LD50 >	100000 1040 40000	mg/kg	Rats Rabbits Mice
Stearic Acid 57-11-4	LD50 >	4640	mg/kg	Rats

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

Chemical Name	Acute Test	Value	Units	Species
Stearic Acid 57-11-4	LD50 >	5000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Not determined.

Corrosivity: Not determined.

Dermal Irritation: Active Ingredient : Did not produce skin irritation in rabbits.

Eye Irritation: Active Ingredient : Produced mild to moderate eye irritation in rabbits.

Sensitization: Active Ingredient : Negative in guinea pig sensitization studies.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Not determined.

Reproductive Effects: Not determined.

Carcinogenicity: Not determined.

Mutagenicity: Active Ingredient : Negative in mutagenicity assays.

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
Nicotinic Acid 59-67-6	60-90	520	Oncorhynchus mykiss	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Nicotinic Acid 59-67-6	60-90	77	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Nicotinic Acid 59-67-6	60-90	90	Desmodesmus subspicatus	72 Hours

12.2. Persistence and degradability

Readily biodegradable.

Chemical Name	Percent	% Degradation	Duration
Nicotinic Acid 59-67-6	60-90	100	Unspecified

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 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
Nicotinic Acid 59-67-6	Present	X	X	Not listed.	X
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed.	X
Kollidon 9003-39-8	-	X	X	Not listed.	X
Stearic Acid 57-11-4	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Nicotinic Acid 59-67-6	Present	-	X	X	Present	HSR003773

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Hydroxypropyl Methylcellulose 9004-65-3	Present	-	X	X	Present	
Kollidon 9003-39-8	Present	-	X	X	Present	
Stearic Acid 57-11-4	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:
Nicotinic Acid	60-90	Not Listed	Not Listed	Not Listed
Hydroxypropyl Methylcellulose	10-30	Not Listed	Not Listed	Not Listed
Kollidon	1-10	Not Listed	Not Listed	Not Listed
Stearic Acid	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):
Nicotinic Acid	60-90	No	Not Applicable	Not applicable
Hydroxypropyl Methylcellulose	10-30	No	Not Applicable	Not applicable
Kollidon	1-10	No	Not Applicable	Not applicable
Stearic Acid	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

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
H319 - Causes serious eye irritation

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

Issued: Jun-13-2013

Supersedes the SDS dated: Jul-24-2008

Disclaimer:
The information and recommendations contained herein are based upon tests believed to be reliable. However, AbbVie Inc. does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. AbbVie Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.