

**Product Name:** Advicor Tablets  
**Issued:** Jun-12-2013

## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** Advicor Tablets

**Synonyms:** Niacin/Lovastatin Tablets; Advicor Tablets, 500 mg/20 mg; Advicor Tablets, 1000 mg/20 mg; Advicor Tablets, 1000 mg/40 mg; Advicor Tablets, 750 mg/20 mg; Advicor Tablets

**Trade name:** Advicor

**List Number:** 3005; 3007; 3010; 3072

#### **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**

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## 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<br>59-67-6                  | 60-80   | Present              | Xi, R36            | Eye Irrit. 2 (H319)               | No data available |
| Hydroxypropyl Methylcellulose<br>9004-65-3 | 15-30   | NA                   |                    | Not Hazardous*                    | No data available |
| Kollidon<br>9003-39-8                      | 1-9.9   | NA                   |                    | Not Hazardous*                    | No data available |
| Lovastatin<br>75330-75-5                   | 1-2.5   | NA                   | R63                | Repr. 2 (H361)                    | No data available |
| Titanium Dioxide<br>13463-67-7             | 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.

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**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:** No signs and symptoms from occupational exposure are known. Clinical data suggests the following: gastrointestinal upset, flushing, pruritus, hypotension, dizziness, fast heart rate, 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

#### **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.

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#### **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:**

| <b>Chemical Name</b>                       | <b>Employee Exposure Limit</b> | <b>Skin Notation</b> |
|--|--------------------------------|----------------------|
| Nicotinic Acid<br>59-67-6                  | 1000 mcg/m <sup>3</sup>        | None                 |
| Hydroxypropyl Methylcellulose<br>9004-65-3 | Not Applicable                 | None                 |
| Kollidon<br>9003-39-8                      | Not Applicable                 | None                 |
| Lovastatin<br>75330-75-5                   | 40 mcg/m <sup>3</sup>          | None                 |
| Titanium Dioxide<br>13463-67-7             | Not Applicable                 | None                 |

| <b>Chemical Name</b>                       | <b>ACGIH TLV</b>  | <b>France</b>             | <b>German MAK</b> | <b>Ireland</b>  | <b>Italy</b> |
|--|---|---------------------------|-------------------|---|--------------|
| Nicotinic Acid<br>59-67-6                  | 3 mg/m <sup>3</sup> for respirable particles and 10 mg/m <sup>3</sup> for inhalable particles |                           |                   |   |              |
| Hydroxypropyl Methylcellulose<br>9004-65-3 | 10 mg/m <sup>3</sup> total dust; 3 mg/m <sup>3</sup> respirable dust                          |                           |                   |   |              |
| Kollidon<br>9003-39-8                      | 10 mg/m <sup>3</sup> for nuisance dust; 3 mg/m <sup>3</sup> respirable particulate            |                           |                   |   |              |
| Titanium Dioxide<br>13463-67-7             | 10 mg/m <sup>3</sup> TWA  | TWA: 10 mg/m <sup>3</sup> |                   | 10 mg/m <sup>3</sup> (TWA)<br>4 mg/m <sup>3</sup> (TWA) |              |

| <b>Chemical Name</b>           | <b>The Netherlands</b> | <b>Spain</b>               | <b>Switzerland</b>        | <b>UK OEL/MEL</b>   |
|--------------------------------|------------------------|----------------------------|---------------------------|---|
| Titanium Dioxide<br>13463-67-7 |                        | 10 mg/m <sup>3</sup> (TWA) | 3 mg/m <sup>3</sup> (TWA) | 30 mg/m <sup>3</sup> (STEL)<br>12 mg/m <sup>3</sup> (STEL)<br>10 mg/m <sup>3</sup> (TWA)<br>4 mg/m <sup>3</sup> (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.

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**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:** 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):** Slightly 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

Not determined

## Section 10. Stability and reactivity

### 10.1. Reactivity

Not determined

### 10.2. Chemical stability

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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 (NO<sub>x</sub>)

## **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.

| <b>Chemical Name</b>                       | <b>Acute Test</b> | <b>Value</b> | <b>Units</b> | <b>Species</b> |
|--|-------------------|--------------|--------------|----------------|
| Nicotinic Acid<br>59-67-6                  | LD50 =            | 3720         | mg/kg        | Mice           |
|  |                   | 4550         |              | Rabbits        |
|  |                   | 7000         |              | Rats           |
| Hydroxypropyl Methylcellulose<br>9004-65-3 | LD50 >            | 2250         | mg/kg        | Rats           |
| Kollidon<br>9003-39-8                      | LD50 =            | 100000       | mg/kg        | Rats           |
|  |                   | 1040         |              | Rabbits        |
|  |                   | 40000        |              | Mice           |
| Lovastatin<br>75330-75-5                   | LD50 >            | 5000         | mg/kg        | Rats           |
|  | LD50 =            | 20,000       |              | Mice           |

**Acute Toxicity - Dermal:** Not determined.

**Acute Toxicity - Inhalation:** Not determined.

**Corrosivity:** Not determined.

**Dermal Irritation:** Major ingredient: Did not produce skin irritation in rabbits.

**Eye Irritation:** Major ingredient: Produced mild to moderate eye irritation in rabbits.

**Sensitization:** Major Ingredient : Negative in guinea pig sensitization studies.

**Toxicokinetics/Metabolism:** Not determined.

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

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| Chemical Name                  | Target Organs: | Species | Dosage | Units | Route      | Duration |
|--------------------------------|----------------|---------|--------|-------|------------|----------|
| Titanium Dioxide<br>13463-67-7 | Lungs          | Rats    | 10,000 | mg/L  | Inhalation | 2 years  |

**Reproductive Effects:** Active Ingredient : In animals adverse reproductive effects include: fetal abnormalities.  
Data for component (s) given below.

| Chemical Name            | Species      | Dosage | Units | Route | Duration         |
|--------------------------|--------------|--------|-------|-------|------------------|
| Lovastatin<br>75330-75-5 | Rats<br>Mice | 80     | mg/kg | Oral  | During Gestation |

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

| Chemical Name                  | Site of Tumors | Species | Dosage  | Route      | Units | Duration |
|--------------------------------|----------------|---------|---------|------------|-------|----------|
| Titanium Dioxide<br>13463-67-7 | Lungs          | Rats    | 250,000 | Inhalation | mg/L  | 2 years  |

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

| Chemical Name            | Micronucleus Assay | Ames Test: | Mouse Lymphoma Assay | Chromosomal Abbr. Assay |
|--------------------------|--------------------|------------|----------------------|-------------------------|
| Lovastatin<br>75330-75-5 | No Data.           | Negative   | No Data.             | Negative                |

**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<br>59-67-6 | 60-80   | 520          | Oncorhynchus mykiss | 96 Hours |

| Chemical Name             | Percent | EC 50 (mg/l) | Species       | Duration |
|---------------------------|---------|--------------|---------------|----------|
| Nicotinic Acid<br>59-67-6 | 60-80   | 77           | Daphnia magna | 48 Hours |

| Chemical Name             | Percent | EB 50/ErC 50 (mg/l) | Species                 | Duration |
|---------------------------|---------|---------------------|-------------------------|----------|
| Nicotinic Acid<br>59-67-6 | 60-80   | 90                  | Desmodesmus subspicatus | 72 Hours |

### 12.2. Persistence and degradability

Major Ingredient : Readily biodegradable.  
Data for component (s) given below.

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| Chemical Name             | Percent | % Degradation | Duration    |
|---------------------------|---------|---------------|-------------|
| Nicotinic Acid<br>59-67-6 | 60-80   | 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**



**Product Name:** Advicor Tablets  
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| Chemical Name                              | EINECS/ ELINCS | TSCA | DSL | NDSL        | PICCS |
|--|----------------|------|-----|-------------|-------|
| Nicotinic Acid<br>59-67-6                  | Present        | X    | X   | Not listed. | X     |
| Hydroxypropyl Methylcellulose<br>9004-65-3 | -              | X    | X   | Not listed. | X     |
| Kollidon<br>9003-39-8                      | -              | X    | X   | Not listed. | X     |
| Lovastatin<br>75330-75-5                   | -              | -    | -   | Not listed. | -     |
| Titanium Dioxide<br>13463-67-7             | Present        | X    | X   | Not listed. | X     |

| Chemical Name                              | ENCS    | ISHL | IECSC | AICS | KECL    | New Zealand |
|--|---------|------|-------|------|---------|-------------|
| Nicotinic Acid<br>59-67-6                  | Present | -    | X     | X    | Present | HSR003773   |
| Hydroxypropyl Methylcellulose<br>9004-65-3 | Present | -    | X     | X    | Present |             |
| Kollidon<br>9003-39-8                      | Present | -    | X     | X    | Present |             |
| Lovastatin<br>75330-75-5                   | -       | -    | X     | -    | -       |             |
| Titanium Dioxide<br>13463-67-7             | 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                | 60-80   | Not Listed | Not Listed | Not Listed |
| Hydroxypropyl Methylcellulose | 15-30   | Not Listed | Not Listed | Not Listed |
| Kollidon                      | 1-9.9   | Not Listed | Not Listed | Not Listed |
| Lovastatin                    | 1-2.5   | Not Listed | Not Listed | Not Listed |
| Titanium Dioxide              | 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                | 60-80   | No                 | Not Applicable               | Not applicable      |
| Hydroxypropyl Methylcellulose | 15-30   | No                 | Not Applicable               | Not applicable      |
| Kollidon                      | 1-9.9   | No                 | Not Applicable               | Not applicable      |
| Lovastatin                    | 1-2.5   | No                 | Not Applicable               | Not applicable      |
| Titanium Dioxide              | 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.

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**Proposition 65 Status:** Chemicals known to the State of California to cause cancer or reproductive harm listed below.

**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.

|                                      |
|--------------------------------------|
| <b>Section 16. Other information</b> |
|--------------------------------------|

**Risk Phrases:** R36 - Irritating to eyes

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

H319 - Causes serious eye irritation, H361 - Suspected of damaging fertility or the unborn child if inhaled

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

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