SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Vicodin ES Tablets
Synonyms: Vicodin ES; Vicodin Tablets, 7.5 mg/750 mg; Vicodin ES (Hydrocodone Bitartrate and Acetaminophen) Tablets
Trade name: Vicodin
List Number: 1973

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
Acute oral toxicity Category 4
Chronic aquatic toxicity Chronic toxicity 3

Classification according to EU Directives 67/548/EEC or 1999/45/EC
Indication of danger: Xn - Harmful
Risk Phrases: R22 - Harmful if swallowed
R52 - Harmful to aquatic organisms
R53 - May cause long-term adverse effects in the aquatic environment

2.2 Label elements
**Section 2. Hazards identification**

**Signal Word:** Warning

**Hazard Statements:**
- H302 - Harmful if swallowed
- H412 - Harmful to aquatic life with long lasting effects
- P264 - Wash face, hands and any exposed skin thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
- P330 - Rinse mouth
- P273 - Avoid release to the environment
- P501 - Dispose of contents/container to an approved waste disposal plant

**2.3 Other hazards**

Not determined

**Section 3. Composition/information on ingredients**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>EINECS/ELINCS Number</th>
<th>EEC Classification</th>
<th>EU - GHS Substance Classification</th>
<th>REACH No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 103-90-2</td>
<td>97-99</td>
<td>Present</td>
<td>Xn, R22 R52-53</td>
<td>Acute Tox. 4 (H302) Aquatic Chronic 3 (H412)</td>
<td>No data available</td>
</tr>
<tr>
<td>Silica, Amorphous 112926-00-8</td>
<td>0.1-1</td>
<td>NA</td>
<td></td>
<td>Not Hazardous*</td>
<td>No data available</td>
</tr>
<tr>
<td>Hydrocodone Bitartrate 34195-34-1</td>
<td>&lt; 1</td>
<td>NA</td>
<td>Xn, R22; R42, R43, R67</td>
<td>STOT SE 3 (H336) Resp. Sens. 1 (H334) Skin Sens. 1 (H317) Acute Tox. 4 (H302)</td>
<td>No data available</td>
</tr>
<tr>
<td>Magnesium Stearate 557-04-0</td>
<td>0.1-1</td>
<td>Present</td>
<td></td>
<td>Not Hazardous*</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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: Clinical data suggests the following: lightheadedness, dizziness, sedation, nausea, vomiting, cognitive dysfunction, incoordination, respiratory distress, rash, anorexia, abnormal liver function, abnormal kidney function, altered white blood cells and thrombocytes.

Medical Conditions Aggravated by Exposure: Data suggest any pre-existing ailments in the following organs: central nervous system, respiratory system, skin, urinary bladder, gastrointestinal system, kidneys. 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.

**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:**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Employee Exposure Limit</th>
<th>Skin Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 103-90-2</td>
<td>1000 mcg/m³</td>
<td>None</td>
</tr>
<tr>
<td>Silica, Amorphous 112926-00-8</td>
<td>Not Applicable</td>
<td>None</td>
</tr>
<tr>
<td>Hydrocodone Bitartrate 14195-34-1</td>
<td>5 mcg/m³ TWA</td>
<td>None</td>
</tr>
<tr>
<td>Magnesium Stearate 557-04-0</td>
<td>Not Applicable</td>
<td>None</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>France</th>
<th>German MAK</th>
<th>Ireland</th>
<th>Italy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 103-90-2</td>
<td></td>
<td></td>
<td>10 mg/m³ (TWA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Silica, Amorphous 112926-00-8</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium Stearate 557-04-0</td>
<td>10 mg/m³ total dust</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>The Netherlands</th>
<th>Spain</th>
<th>Switzerland</th>
<th>UK OEL/MEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 103-90-2</td>
<td></td>
<td></td>
<td></td>
<td>30 mg/m³ (STEL)</td>
</tr>
<tr>
<td>Silica, Amorphous 112926-00-8</td>
<td></td>
<td></td>
<td></td>
<td>10 mg/m³ (TWA)</td>
</tr>
</tbody>
</table>

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8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions. Use inside a process enclosure when handling the bulk formulation.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>White Tablet</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless.</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not determined</td>
</tr>
<tr>
<td>pH</td>
<td>Not determined</td>
</tr>
<tr>
<td>Boiling Pt. @ 760 mm Hg (°C)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Flash Point (°C)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Evaporation Rate at 20°C</td>
<td>Not determined</td>
</tr>
<tr>
<td>Flammability (Solid)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Lower Explosive Limit</td>
<td>Not determined</td>
</tr>
<tr>
<td>Upper Explosive Limit</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not determined</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not determined</td>
</tr>
<tr>
<td>Autoignition Temp. (°C)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Decomposition temperature (°C)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Viscosity (centipoise)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Explosion Severity</td>
<td>Not determined</td>
</tr>
<tr>
<td>Oxidizer Properties</td>
<td>Not determined</td>
</tr>
</tbody>
</table>

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
Not determined.

10.5 Incompatible materials
Not determined

10.6 Hazardous decomposition products
Carbon oxides, Nitrogen oxides (NOx)

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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Acute Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 103-90-2</td>
<td>LD50 =</td>
<td>338</td>
<td>mg/kg</td>
<td>Mice</td>
</tr>
<tr>
<td>Hydrocodone Bitartrate 54195-34-1</td>
<td>LD50 =</td>
<td>375</td>
<td>mg/kg</td>
<td>Rats</td>
</tr>
</tbody>
</table>

Acute Toxicity - Dermal: Not determined.

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium Stearate 557-04-0</td>
<td>LC 50 &gt;</td>
<td>2000</td>
<td>mg/m³, 1 hour</td>
<td>Rats</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Test Type</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone Bitartrate 54195-34-1</td>
<td>LD50 (sc) =</td>
<td>150</td>
<td>mg/kg</td>
<td>Rats</td>
<td>None.</td>
</tr>
<tr>
<td></td>
<td>66</td>
<td>mg/kg</td>
<td>Mice</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Corrosivity: Not determined.
Product Name: Vicodin ES Tablets  
Issued: Jun-14-2013

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Minor Ingredient: May cause allergic respiratory and skin reactions.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Minor Ingredient: May cause drowsiness or dizziness
Data for component (s) given below.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Target Organs:</th>
<th>Species</th>
<th>Dosage</th>
<th>Units</th>
<th>Route</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 103-90-2</td>
<td>Lymphatic system, Liver, Kidney,</td>
<td>Rats, Mice</td>
<td>600</td>
<td>mg/kg</td>
<td>Oral Diet</td>
<td>Repeat dose study (ies)</td>
</tr>
<tr>
<td></td>
<td>Thyroid, Testes, Ovaries, Uterus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reproductive Effects: Not determined.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Species</th>
<th>Dosage</th>
<th>Units</th>
<th>Route</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone Bitartrate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Carcinogenicity: Not determined.

Mutagenicity: Data for component (s) given below.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Micronucleus Assay</th>
<th>Ames Test:</th>
<th>Mouse Lymphoma Assay</th>
<th>Chromosomal Abbr. Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 103-90-2</td>
<td>No Data.</td>
<td>Negative</td>
<td>No Data.</td>
<td>Positive</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>LC 50 (mg/l)</th>
<th>Species</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 103-90-2</td>
<td>97.99</td>
<td>814</td>
<td>Fathead Minnow</td>
<td>96 Hours</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>EC 50 (mg/l)</th>
<th>Species</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen 103-90-2</td>
<td>97.99</td>
<td>9.2</td>
<td>Daphnia magna</td>
<td>48 Hours</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>EINECS/ ELINCS</th>
<th>TSCA</th>
<th>DSL</th>
<th>NDSL</th>
<th>PICCS</th>
</tr>
</thead>
</table>

Page 8 of 10
### Chemical Name

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ENCS</th>
<th>ISHL</th>
<th>IECSC</th>
<th>AICS</th>
<th>KECL</th>
<th>New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>Present</td>
<td>Present</td>
<td>X</td>
<td>X</td>
<td>Present</td>
<td>HSR005203</td>
</tr>
<tr>
<td>Silica, Amorphous</td>
<td>Present</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>Hydrocodone Bitartrate</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>Present</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>Present</td>
<td></td>
</tr>
</tbody>
</table>

### Legend

ENEC/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
ENC - 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:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>NTP:</th>
<th>IARC:</th>
<th>ACGIH:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>97-99</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Silica, Amorphous</td>
<td>0.1-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Hydrocodone Bitartrate</td>
<td>&lt; 1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>0.1-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

### SARA 313 Information

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>SARA 313 Chemical:</th>
<th>CERCLA RQ/SARA EHS RQ (lbs):</th>
<th>SARA EHS TPQ (lbs):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>97-99</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Silica, Amorphous</td>
<td>0.1-1</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Hydrocodone Bitartrate</td>
<td>&lt; 1</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>0.1-1</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### 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:
Exempt

### NFPA Rating:
Health: 2
15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R22 - Harmful if swallowed, R52 - Harmful to aquatic organisms, R53 - May cause long-term adverse effects in the aquatic environment

Full text of H-Statements referred to under sections 2 and 3
H302 - Harmful if swallowed, H412 - Harmful to aquatic life with long lasting effects, H336 - May cause drowsiness or dizziness, H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled, H317 - May cause an allergic skin reaction

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

Issued: Jun-14-2013

Supersedes the SDS dated: Oct-25-2001

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