1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier
Product Name Norco

Other means of identification
Product Code FG00095
Synonyms Hydrocodone Bitartrate and Acetaminophen

Recommended use of the chemical and restrictions on use
Recommended Use Opioid Analgesic and Antitussive for management of moderate to severe pain

This safety data sheet is written to provide health, safety, and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525
E-mail address SDS@Allergan.com

Emergency telephone number
Emergency Telephone Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification
OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation</td>
<td>Category 1</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Category 1</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>Category 1</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>Category 1</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Category 2</td>
</tr>
<tr>
<td>Specific target organ toxicity (single exposure)</td>
<td>Category 2 (H371)</td>
</tr>
<tr>
<td>Specific target organ toxicity (repeated exposure)</td>
<td>Category 2</td>
</tr>
</tbody>
</table>

Label elements

Emergency Overview

Hazard statements
H314 - Causes severe skin burns and eye damage
H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H361 - Suspected of damaging fertility or the unborn child
<table>
<thead>
<tr>
<th>Appearance</th>
<th>Tablet</th>
<th>Physical state</th>
<th>Solid</th>
<th>Odor</th>
<th>No information available</th>
</tr>
</thead>
</table>

### Chemical Name

#### ACETAMINOPHEN DC90

**Symptoms**
The most frequently reported adverse reactions are lightheadedness, dizziness, sedation, nausea, and vomiting. Less common effects can include blurred or double vision or other changes in vision, constipation, dry mouth, false sense of well-being, general feeling of discomfort or illness, headache, loss of appetite, nervousness or restlessness, nightmares or unusual dreams, trouble in sleeping. Rarely symptoms can include black, tarry stools, bloody or cloudy urine, confusion, dark urine, difficult or painful urination, fast, slow, or pounding heartbeat, frequent urge to urinate, hallucinations (seeing, hearing, or feeling things that are not there), increased sweating, irregular breathing or wheezing, mental depression, pain in lower back and/or side (severe and/or sharp), pale stools, pinpoint red spots on skin, redness or flushing of face, ringing or buzzing in ears, skin rash, hives, or itching, sore throat and fever, sudden decrease in amount of urine, swelling of face, trembling or uncontrolled muscle movements, unusual bleeding or bruising, unusual excitement (especially in children), yellow eyes or skin. Abrupt cessation of use of this medication can cause the following symptoms: body aches, diarrhea, fast heartbeat, fever, runny nose, or sneezing, gooseflesh, increased sweating, increased yawning, loss of appetite, nausea or vomiting, nervousness, restlessness, or irritability, shivering or trembling, stomach cramps, trouble in sleeping, weakness.

#### POVIDONE USP(PLASDONE K-29-32)

Possible eye, skin, gastrointestinal and/or respiratory tract irritation. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Overdose effects from ingestion of large amounts include abdominal cramps, flatulence, and fecal impaction.

### Hydrocodone

#### Donepezil HCL

The most common symptoms seen in therapeutic use include: nausea, diarrhea, insomnia, vomiting, muscle cramp, fatigue and anorexia.

### Memantine Hydrochloride

Most common are dizziness, headache, confusion and constipation

### Pre-existing Conditions Aggravated by Exposure

#### ACETAMINOPHEN DC90

Pre-existing acute abdominal conditions, respiratory or neurological disorders, severe impairment of hepatic or renal function, hypothyroidism, Addison’s disease, prostatic hypertrophy or urethral stricture, and narcotic or alcohol addiction may be aggravated by repeated exposure to this product when ingested. These effects may be possible from workplace exposure.

#### POVIDONE USP(PLASDONE K-29-32)

Known hypersensitivity to this medication

#### Hydrocodone

Known hypersensitivity to this medication

#### Donepezil HCL

When administered for therapeutic use, pre-existing asthma, ulcers, cardiac abnormalities, hepatic, bladder and neurological conditions may be aggravated by exposure

#### Memantine Hydrochloride

Contraindication include hypersensitivity to any component of this product hepatic impairment

Precautionary statements

P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting

P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P285 - In case of inadequate ventilation wear respiratory protection
P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
P310 - Immediately call a POISON CENTER or doctor/physician
P285 - In case of inadequate ventilation wear respiratory protection
P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P363 - Wash contaminated clothing before reuse
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P363 - Wash contaminated clothing before reuse
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P363 - Wash contaminated clothing before reuse
P285 - In case of inadequate ventilation wear respiratory protection

Other Information
Unknown Acute Toxicity
34.61% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, they can be considered hazardous.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULOSE/AVICEL PH102</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>30 - 60*</td>
</tr>
<tr>
<td>CROSCARMELLOSE SODIUM NF (TYPE A, AC-DI-SOL)</td>
<td>74811-65-7</td>
<td>N/A</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>POVIDONE USP/PLASDONE K-29-32</td>
<td>9003-39-8</td>
<td>N/A</td>
<td>7 - 13*</td>
</tr>
<tr>
<td>ACETAMINOPHEN DC90</td>
<td>103-90-2</td>
<td>203-157-5</td>
<td>7 - 13*</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>125-29-1</td>
<td>204-733-9</td>
<td>3 - 7*</td>
</tr>
<tr>
<td>LACTOSE MONOHYDRATE NF (FAST FLOW, SPRAY DRIED)</td>
<td>64044-51-5</td>
<td>N/A</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>Trospium Chloride</td>
<td>10405-02-4</td>
<td>233-875-4</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>Titanium Dioxide</td>
<td>1317-70-0</td>
<td>215-280-1</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>CORN STARCH NF</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>MAGNESIUM STEARATE NF (VEGETABLE SOURCE)</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>STEARIC ACID NF</td>
<td>57-11-4</td>
<td>200-313-4</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>TALC USP (1656)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>Sucrose Palmitate</td>
<td>26446-38-8</td>
<td>247-706-7</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>PWDRD CELLULOSE BW40 NF</td>
<td>9004-32-4</td>
<td>N/A</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>FERRIC OXIDE NF (RED 30)</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>COLOIDAL SILICON DIOXIDE (CAB-O-SIL GRADE M-5P)</td>
<td>112945-52-5</td>
<td>N/A</td>
<td>0.1 - 1*</td>
</tr>
<tr>
<td>POLYETHYLENE GLYCOL NF6000</td>
<td>25833-68-3</td>
<td>N/A</td>
<td>0.1 - 1*</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

First aid measures

Eye contact
Rinse immediately with plenty of water and seek medical advice.

Skin Contact
Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation
Remove to fresh air.

Ingestion
Consult a physician if necessary.

Chemical Name

Note to physicians
ACETAMINOPHEN DC90
This product is contraindicated for patients with hypersensitivity or intolerance to any component of product, and patients with porphyria. Acetaminophen has been associated with cases of acute liver failure, at time resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product.

Hydrocodone
Treat symptomatically.

Donepezil HCL
Overdosage with cholinesterase inhibitors can result in cholinergic crisis characterized by severe nausea, vomiting, salivation, sweating, bradycardia, hypotension, respiratory depression, collapse and convulsions. Increasing muscle weakness is a possibility and may result in death if respiratory muscles are involved. Tertiary anticholinergics such as atropine may be used as an antidote for ARICEPT overdosage. Intravenous atropine sulfatetitrated to effect is recommended: an initial dose of 1.0 to 2.0 mg IV with subsequent doses based upon clinical response.

Memantine Hydrochloride
Conditions that raise urine pH may decrease urinary elimination of Memantine, resulting in increased plasma levels of memantine.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
Fire may produce irritating, corrosive and/or toxic gases.

Explosion data
Sensitivity to Mechanical Impact
Not impact sensitive.

Sensitivity to Static Discharge
Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions
See Section 12 for additional ecological information.

Methods for containment
Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling
Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

Storage Conditions
Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

Incompatible materials
None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergan OEL (ug/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULO(avicel PH102) 9004-34-6</td>
<td>TWA: 10 mg/m³</td>
<td>TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction (vacated) TWA: 5 mg/m³ (vacated) STEL: 10 mg/m³</td>
<td>TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust TWA: 1 mg/m³</td>
<td>N/A</td>
</tr>
<tr>
<td>ACETAMINOPHEN DC90 103-90-2</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>1000 ug/m³</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>70</td>
</tr>
<tr>
<td>Trospium Chloride 125-29-1</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>100 ug/m³</td>
</tr>
<tr>
<td>CORN STARCH NF 9005-25-8</td>
<td>TWA: 10 mg/m³</td>
<td>TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction (vacated) TWA: 5 mg/m³ (vacated) STEL: 10 mg/m³</td>
<td>TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust</td>
<td>N/A</td>
</tr>
<tr>
<td>MAGNESIUM STEARATE NF(VEGETABLE SOURCE) 557-04-0</td>
<td>TWA: 10 mg/m³ inhalable particulate matter TWA: 3 mg/m³ respirable particulate matter TWA: 10 mg/m³ inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m³ respirable particulate matter except stearates of toxic metals</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Material</td>
<td>CAS Number</td>
<td>TWA: 10 mg/m³ inhalable particulate matter</td>
<td>TWA: 3 mg/m³ respirable particulate matter</td>
<td>N/A</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>------------</td>
<td>-------------------------------------------</td>
<td>-------------------------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>STEARIC ACID NF 57-11-4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TALC USP(1656) 14807-96-6</td>
<td></td>
<td>TWA: 2 mg/m³ particulate matter containing no asbestos and &lt;1% crystalline silica, respirable particulate matter</td>
<td>(vacated) TWA: 2 mg/m³ respirable dust &lt;1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more; use Quartz limit</td>
<td>IDLH: 1000 mg/m³ TWA: 2 mg/m³ containing no Asbestos and &lt;1% Quartz respirable dust</td>
</tr>
<tr>
<td>FERRIC OXIDE NF (RED 30) 1309-37-1</td>
<td></td>
<td>TWA: 5 mg/m³ respirable particulate matter</td>
<td>TWA: 10 mg/m³ fume TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 10 mg/m³ fume and total dust Iron oxide (vacated) TWA: 5 mg/m³ respirable fraction regulated under Rouge</td>
<td>IDLH: 2500 mg/m³ Fe dust and fume TWA: 5 mg/m³ Fe dust and fume</td>
</tr>
<tr>
<td>White Cresin Wax 8002-74-2</td>
<td></td>
<td>TWA: 2 mg/m³ fume (vacated) TWA: 2 mg/m³</td>
<td>TWA: 2 mg/m³ fume</td>
<td>N/A</td>
</tr>
<tr>
<td>Donepezil HCL 120011-70-3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Memantine Hydrochloride 41100-52-1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NIOSH IDLH Immediately Dangerous to Life or Health**

**Other Information**

Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

**Appropriate engineering controls**

**Engineering Controls**

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

**Skin and body protection**

During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

**Respiratory protection**

Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Information on basic physical and chemical properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Appearance</th>
<th>Odor</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
<td>Tablet</td>
<td>No information available</td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>No information available</td>
<td>No information available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
<td>No information available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.
Possibility of Hazardous Reactions
None under normal processing.
Conditions to avoid
Aerosol formation.
Incompatible materials
None known based on information supplied.
Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETAMINOPHEN DC90</td>
<td>Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Inhalation of large amounts may cause lung edema, dizziness, and respiratory difficulties.</td>
<td>See Symptoms for more information.</td>
<td>Prolonged contact may cause redness and irritation.</td>
<td>Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product caused by poor hygiene practices can cause nausea, vomiting, sweating, general malaise, respiratory depression, somnolence progressing to stupor or coma, skeletal</td>
</tr>
</tbody>
</table>
muscle flaccidity, cold and clammy skin, slow heartbeat, low blood pressure, temporary absence or cessation of breathing, circulatory collapse, cardiac arrest, hepatic necrosis, hypoglycemic coma, thrombocytopenia, and death. Repeated ingestion may lead to chemical dependency. Ingestion of large amounts of this product may be fatal. The toxic dose for adults for acetaminophen is 10 g. Ingestion of this product may cause serious hypersensitivity reaction in persons susceptible to Acetaminophen, as described under “Sensitization to the Product”. Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced.

Hydrocodone

No data available.

No data available.

Products containing NSAIDs, including hydrocodone bitartrate and ibuprofen tablets, can cause serious adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, which can be fatal.

Trospium Chloride

If airborne dusts generated by this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

Contact with the eyes of airborne dusts generated by this compound may cause mild to moderate irritation, redness, and tearing (mechanical irritation).

In therapeutic use, this compound has caused swelling of the skin, rash and anaphylactic reactions. Angioedema of the face, lips, tongue and/or larynx has been reported with therapeutic use of Trospium. Angioedema associated with upper airway swelling may be life threatening. May cause irritation to skin. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).

If this compound is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

Donepezil HCL

Inhalation of this compound may irritate the nose, throat, and lungs. No information is available on other possible effects.

Contact with the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.

Contact with the skin may cause irritation. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).

Ingestion is not a significant route of occupational overexposure. If swallowed, irritation of the gastrointestinal tract may occur with nausea, vomiting, and diarrhea.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULO (AVICEL PH102)</td>
<td>&gt; 5 g/kg (Rat)</td>
<td>&gt; 2 g/kg (Rabbit)</td>
<td>&gt; 5800 mg/m³ (Rat) 4 h</td>
</tr>
<tr>
<td>POVIDONE USP (PLASDONE K-29-32)</td>
<td>= 100 g/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### Delayed and immediate effects as well as chronic effects from short and long-term exposure

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>POVIDONE USP (PLASDONE K-29-32)</td>
<td>No information available.</td>
<td>Not suspected of being a human carcinogen.</td>
<td>No information available.</td>
<td>No information available</td>
</tr>
<tr>
<td>ACETAMINOPHEN DC90</td>
<td>No information available.</td>
<td>Not suspected of being a human carcinogen.</td>
<td>Possible risk of harm to the unborn child.</td>
<td>Detectable amounts of this compound have been identified in the milk of nursing women receiving this drug. Caution should be exercised when taking this compound is administered to nursing women.</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>No information available.</td>
<td>No information available.</td>
<td>Suspected Reproductive Toxicant.</td>
<td>It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.</td>
</tr>
<tr>
<td>Tropium Chloride</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>Animal studies in mice and rats have not shown carcinogenicity.</td>
<td>Studies in rats and rabbits have not shown statistically significant levels of teratogenicity or harm to the fetus.</td>
<td>Detectable amounts of this compound have been identified in the milk of nursing women receiving this drug. Caution should be exercised when taking this compound is administered to nursing women.</td>
</tr>
<tr>
<td>Donepezil HCL</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>Not suspected of being a human carcinogen.</td>
<td>This product does not contain any known or suspected reproductive hazards.</td>
<td>No information available</td>
</tr>
<tr>
<td>Memantine Hydrochloride</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>Animal studies in mice and rats have not shown carcinogenicity.</td>
<td>Studies in rats have not shown fertility impairment. Decreased pup weights and an increase in incompletely ossified vertebrae was observed at slightly maternally toxic doses with the NOEL of approximately 3 times the maximum recommended human therapeutic dose.</td>
<td>It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to nursing mothers.</td>
</tr>
<tr>
<td>Oleic Acid</td>
<td>Not Suspected of being a Mutagen.</td>
<td>Not suspected of being a human carcinogen.</td>
<td>Not suspected of being a reproductive hazard.</td>
<td>No information available</td>
</tr>
</tbody>
</table>
Chemical Name | STOT - single exposure | STOT - repeated exposure
--- | --- | ---
ACETAMINOPHEN DC90 | Potential to produce significant toxicity to specific target organ(s). | Potential to produce significant toxicity to specific target organ(s).

**Chronic toxicity**
May cause adverse liver effects.

**Target Organ Effects**
Central nervous system, Eyes, liver, Respiratory system, Skin.

**Numerical measures of toxicity - Product Information**

**Unknown Acute Toxicity**
34.61% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document.

| ATEmix (oral) | 4350 mg/kg |
| ATEmix (dermal) | 2672 mg/kg |
| ATEmix (inhalation-dust/mist) | 7.8 mg/l |

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**
Toxic to aquatic life with long lasting effects

94.41% of the mixture consists of component(s) of unknown hazards to the aquatic environment

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae/aquatic plants</th>
<th>Fish</th>
<th>Crustacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETAMINOPHEN DC90 103-90-2</td>
<td>N/A</td>
<td>814: 96 h Pimephales promelas mg/L</td>
<td>6.1 - 14: 48 h Daphnia magna mg/L</td>
</tr>
<tr>
<td>TALC USP (1656) 14807-96-6</td>
<td>N/A</td>
<td>100: 96 h Brachydanio rerio g/L LC50</td>
<td>N/A</td>
</tr>
<tr>
<td>Medium Chain Triglycerides 73398-61-5</td>
<td>N/A</td>
<td>N/A</td>
<td>2.2: 24 h Daphnia magna mg/L EC50</td>
</tr>
<tr>
<td>Oleic Acid 112-80-1</td>
<td>N/A</td>
<td>205: 96 h Pimephales promelas mg/L</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Persistence and degradability</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETAMINOPHEN DC90 103-90-2</td>
<td>This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic materials; however, no specific information is known.</td>
<td>No information available</td>
<td>No information available</td>
<td>0.51</td>
</tr>
<tr>
<td>Hydrocodone 125-29-1</td>
<td>No information available</td>
<td>No information available</td>
<td>If released to soil, slight mobility is expected</td>
<td>( \log Kow = 2.16 ) (est)</td>
</tr>
<tr>
<td>Trospium Chloride 10405-02-4</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
<td>( \log P = 0.70 )</td>
</tr>
<tr>
<td>Donepezil HCL 120011-70-3</td>
<td>This compound has not been tested for persistence or biodegradability</td>
<td>Based on the BCF, the potential for bioaccumulation in aquatic organisms is high.</td>
<td>This product has not been tested for mobility in soil</td>
<td>( \log P = 4.708 ) (predict.)</td>
</tr>
<tr>
<td>Memantine Hydrochloride 41100-52-1</td>
<td>N/A</td>
<td>Based on the BCF, the potential for bioaccumulation in aquatic organisms is high.</td>
<td>Low mobility in soil</td>
<td>3.28</td>
</tr>
</tbody>
</table>

**Other adverse effects**
No information available

### 13. DISPOSAL CONSIDERATIONS

**Waste treatment methods**

**Disposal of wastes**
Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging**
Do not reuse container. Dispose of contents/containers in accordance with local regulations.
14. TRANSPORT INFORMATION

DOT Not regulated
TDG Not regulated
ICAO (air) Not regulated
IATA Not regulated
IMDG Not regulated
ADR Not regulated
ADN Not regulated

15. REGULATORY INFORMATION

International Inventories
TSCA Not Listed
DSL/NDSL Not Listed
EINECS/ELINCS Not Listed

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations

Carcinogenicity
The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (AVICEL PH102) 9004-34-6</td>
<td>-</td>
<td>Group 1</td>
<td>Known</td>
<td>X</td>
</tr>
<tr>
<td>Povidone USP/PLASDONE K-29-32 9003-39-8</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Acetaminophen DC90 103-90-2</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Talc USP (1656) 14807-96-6</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>Ferric Oxide NF (RED 30) 1309-37-1</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Colloidal Silicon Dioxide (CAB-O-SIL GRADE M-5P) 112945-52-5</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

IARC (International Agency for Research on Cancer)
Not classifiable as a human carcinogen

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.
SARA 311/312 Hazard Categories

- Acute health hazard: No
- Chronic Health Hazard: No
- Fire hazard: No
- Sudden release of pressure hazard: No
- Reactive Hazard: No

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Proposition 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULO( AVICEL PH102) - 9004-34-6</td>
<td>Carcinogen</td>
</tr>
</tbody>
</table>

U.S. State Right-to-Know Regulations

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULO( AVICEL PH102) 9004-34-6</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Oleic Acid 112-80-1</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>TALC USP(1656) 14807-96-6</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Revision Date 29-Sep-2018
Revision Note No information available
Disclaimer
The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet