SAFETY DATA SHEET

Revision Date 29-Sep-2018 **Version** 2

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 Opiod 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)

Skin corrosion/irritation	Category 1
Serious eye damage/eye irritation	Category 1
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Reproductive toxicity	Category 2
Specific target organ toxicity (single exposure)	Category 2 - (H371)
Specific target organ toxicity (repeated exposure)	Category 2

Label elements

Emergency Overview

Danger

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

H371 - May cause damage to organs
H373 - May cause damage to organs through prolonged or repeated exposure

Appearance Tablet **Physical state** Solid **Odor** No information available

Chemical Name	Symptoms
ACETAMINOPHEN DC90	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	The most common adverse effects of hydrocodone are lightheadedness, dizziness, sedation, nausea, and vomiting. These adverse effects appear to be more prominent in ambulatory patients than in non-ambulatory patients, and some of these effects may be alleviated if the patient lies down. Other adverse effects include constipation, rash, pruritus, euphoria, and dysphoria
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

Chemical Name	Medical 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
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
P321 - Specific treatment (see supplemental first aid instructions on this label)
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
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P309 - IF exposed or if you feel unwell:
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P405 - Store locked up
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/ container to an approved waste disposal plant

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, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

White Cresin Wax	8002-74-2	232-315-6	0.1 - 1*
Medium Chain Triglycerides	73398-61-5	277-452-2	<0.1*
HydroxypropylMethlcellulose K100 Prem	9004-65-3	N/A	<0.1*
ETHYLCELLULOSE NF ETHOCEL 100	9004-57-3	N/A	<0.1*
Donepezil HCL	120011-70-3	N/A	<0.1*
CARNABUA WAX NF	8015-86-9	232-399-4	<0.1*
Memantine Hydrochloride	41100-52-1	255-219-6	<0.1*
Oleic Acid	112-80-1	204-007-1	<0.1*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

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 crisischaracterized by severe nausea, vomiting, salivation, sweating, bradycardia,hypotension, respiratory depression, collapse and convulsions. Increasingmuscle weakness is a possibility and may result in death if respiratorymuscles are involved. Tertiary anticholinergics such as atropine may beused as an antidote for ARICEPT overdosage. Intravenous atropine sulfatetitrated to effect is recommended: an initial dose of 1.0 to 2.0 mg IV withsubsequent 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 .

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m³)
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	TWA: 10 mg/m³	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	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust TWA: 1 mg/m³	N/A
ACETAMINOPHEN DC90 103-90-2	N/A	N/A	N/A	1000 ug/m³
Hydrocodone 125-29-1	N/A	N/A	N/A	70
Trospium Chloride 10405-02-4	N/A	N/A	N/A	100 ug/m^3
CORN STARCH NF 9005-25-8	TWA: 10 mg/m³	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	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust	N/A
MAGNESIUM STEARATE NF(VEGETABLE SOURCE) 557-04-0	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	N/A	N/A	N/A

STEARIC ACID NF 57-11-4	TWA: 10 mg/m³ inhalable particulate matter TWA: 3 mg/m³ respirable particulate matter	N/A	N/A	N/A
TALC USP(1656) 14807-96-6	TWA: 2 mg/m³ particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter	(vacated) TWA: 2 mg/m³ respirable dust <1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more;use Quartz limit	IDLH: 1000 mg/m³ TWA: 2 mg/m³ containing no Asbestos and <1% Quartz respirable dust	N/A
FERRIC OXIDE NF (RED 30) 1309-37-1	TWA: 5 mg/m³ respirable particulate matter	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	IDLH: 2500 mg/m³ Fe dust and fume TWA: 5 mg/m³ Fe dust and fume	N/A
White Cresin Wax 8002-74-2	TWA: 2 mg/m³ fume	(vacated) TWA: 2 mg/m³	TWA: 2 mg/m³ fume	N/A
Donepezil HCL 120011-70-3	N/A	N/A	N/A	17
Memantine Hydrochloride 41100-52-1	N/A	N/A	N/A	67

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

Physical state	Solid	**Appearance**	Tablet
Color	No information available	**Odor**	No information available
Odor threshold	No information available		

Property	Values
pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	No information available
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Other Information

Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

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

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
ACETAMINOPHEN DC90	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.	See Symptoms for more information.	Prolonged contact may cause redness and irritation.	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

				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 bitrate and ibuprofen tablets, can cause serious adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, which can be fatal.	No data available.
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 therapetuic use of Trospium. Angioedema associated with upper airway swelling may be life threatening. May cause irritation to skin. Prolonged or repeated skin contact may caus 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, andlungs. 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 orrepeated 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.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
MICROCRYSTALLINE CELLULO(AVICEL PH102)	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m³ (Rat) 4 h
POVIDONE USP(PLASDONE K-29-32)	= 100 g/kg (Rat)	N/A	N/A

ACETAMINOPHEN DC90	= 1944 mg/kg (Rat)	N/A	N/A
Trospium Chloride	= 1510 mg/kg (Rat)	N/A	N/A
STEARIC ACID NF	= 4600 mg/kg (Rat)	> 5 g/kg (Rabbit)	N/A
PWDRD CELLULOSE BW40 NF	= 27000 mg/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m^3 (Rat) 4 h
FERRIC OXIDE NF (RED 30)	> 10000 mg/kg (Rat)	N/A	N/A
COLOIDAL SILICON DIOXIDE(CAB-O-SIL GRADE M-5P)	= 3160 mg/kg (Rat)	N/A	N/A
White Cresin Wax	> 5000 mg/kg (Rat)	> 3600 mg/kg (Rabbit)	N/A
Medium Chain Triglycerides	> 5000 mg/kg (Rat)	N/A	N/A
ETHYLCELLULOSE NF ETHOCEL 100	> 5 g/kg (Rat)	> 5 g/kg (Rabbit)	N/A
Donepezil HCL	32.6 mg/kg (rat)	N/A	N/A
Memantine Hydrochloride	328 mg/kg Oral Rat (Female)	N/A	N/A
Oleic Acid	= 25 g/kg (Rat)	N/A	N/A

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
POVIDONE USP(PLASDONE K-29-32)	No information available.	Not suspected of being a human carcinogen.	No information available.	No information available
ACETAMINOPHEN DC90	No information available.	Not suspected of being a human carcinogen.	Possible risk of harm to the unborn child.	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.
Hydrocodone	No information available.	No information available.	Suspected Reproductive Toxicant.	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.
Trospium Chloride	Not mutagenic in the standard battery of tests.	Animal studies in mice and rats have not shown carcinogenicity.	Studies in rats and rabbits have not shown statistically significant levels of teratogenicity or harm to the fetus.	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.
Donepezil HCL	Not mutagenic in the standard battery of tests.	Not suspected of being a human carcinogen.	This product does not contain any known or suspected reproductive hazards.	No information available
Memantine Hydrochloride	Not mutagenic in the standard battery of tests.	Animal studies in mice and rats have not shown carcinogenicity.	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.	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.
Oleic Acid	Not Suspected of being a Mutagen.	Not suspected of being a human carcinogen.	Not suspected of being a reproductive hazard.	No information available

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 components(s) of unknown hazards to the aquatic environment

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

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
ACETAMINOPHEN DC90 103-90-2	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.	No information available	No information available	0.51
Hydrocodone 125-29-1	No information available	No information available	If released to soil, slight mobility is expected	log Kow = 2.16 (est)
Trospium Chloride 10405-02-4	No information available	No information available	No information available	Log P = 0.70
Donepezil HCL 120011-70-3	This compound has not been tested for persistence or biodegradability	Based on the BCF, the potential for bioaccumulation in aquatic organisms is high.	This product has not been tested for mobility in soil	Log P = 4.708 (predict.)
Memantine Hydrochloride 41100-52-1	N/A	Based on the BCF, the potential for bioaccumulation in aquatic organisms is high.	Low mobility in soil	3.28

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)

Chemical Name	ACGIH	IARC	NTP	OSHA
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	-	Group 1	Known	X
POVIDONE USP(PLASDONE K-29-32) 9003-39-8	-	Group 3	-	-
ACETAMINOPHEN DC90 103-90-2	-	Group 3	-	-
TALC USP(1656) 14807-96-6	-	Group 3	-	X
FERRIC OXIDE NF (RED 30) 1309-37-1	-	Group 3	-	-
COLOIDAL SILICON DIOXIDE(CAB-O-SIL GRADE M-5P) 112945-52-5	-	Group 3	-	-

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

Chemical Name	California Proposition 65
MICROCRYSTALLINE CELLULO(AVICEL PH102) - 9004-34-6	Carcinogen

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	X	X	X
Oleic Acid 112-80-1	-	-	X
TALC USP(1656) 14807-96-6	X	X	X

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