



SAFETY DATA SHEET

Revision Date 16-Jul-2019

Version 2

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

Product identifier

Product Name Fiorinal

Other means of identification

Product Code FG00166

Synonyms Butalbital, aspirin and caffeine capsules

Recommended use of the chemical and restrictions on use

Recommended Use symptom complex of tension (or muscle contraction) headache

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)

Acute toxicity - Oral	Category 4
Serious eye damage/eye irritation	Category 1
Carcinogenicity	Category 2
Reproductive toxicity	Category 2
Specific target organ toxicity (single exposure)	Category 3 - (H335)

Label elements

Emergency Overview

Danger

Hazard statements

H302 - Harmful if swallowed
H318 - Causes serious eye damage
H351 - Suspected of causing cancer
H361 - Suspected of damaging fertility or the unborn child
H335 - May cause respiratory irritation
H336 - May cause drowsiness or dizziness



Appearance Capsule	Physical state Solid	Odor No information available
Chemical Name BUTALBITAL USP	<p>Symptoms The most frequently reported adverse reactions are drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, abdominal pain, and intoxicated feeling. The following adverse events are classified as infrequent: headache, shaky feeling, tingling, agitation, fainting, fatigue, heavy eyelids, high energy, hot spells, numbness, sluggishness, seizure. Mental confusion, excitement, or depression can also occur due to intolerance, particularly in elderly or debilitated patients, or due to overdosage of this medication.</p>	
ASPIRIN USP (80 MESH)	<p>Employees administering the product should not experience adverse effects if handled properly. Adverse effects from therapeutic doses have included the following: Headache, shaky feeling, tingling, agitation, fainting, fatigue, heavy eyelids, high energy, hot spells, numbness, and sluggishness, abuse, addiction, anxiety, depression, disorientation, hallucination, hyperactivity, insomnia, libido decrease, nervousness, neuropathy, psychosis, sedation, sexual activity increase, slurred speech, twitching, unconsciousness, vertigo; Dry mouth, hyperhidrosis, epistaxis, flushing, miosis, salivation; Vomiting, difficulty swallowing, heartburn, anorexia, appetite increased, constipation, diarrhea, esophagitis, gastroenteritis, gastrointestinal spasm, hiccup, mouth burning, pyloric ulcer, chest pain, hypotensive reaction, palpitations, syncope; Tachycardia; Leg pain and muscle fatigue; Diuresis; Pruritus, fever, earache, nasal congestion, tinnitus, allergic reaction, anaphylactic shock, cholangiocarcinoma, drug interaction with erythromycin (stomach upset), edema; Erythema, erythema multiforme, exfoliative dermatitis, hives, rash, toxic epidermal necrolysis; Kidney impairment, urinary difficulty.</p>	
CAFFEINE USP(ANHYDROUS & PREMILLED)	<p>Cardiac stimulation, irritability, tremor, dependence, nephrotoxicity, hyperglycemia. Adverse effects may include nervousness, tremors, nausea, vomiting, diarrhea, increased urination and trouble sleeping. Possible allergic reaction to material if inhaled, ingested or in contact with skin.</p>	
Donepezil HCL	<p>The most common symptoms seen in therapeutic use include: nausea, diarrhea, insomnia, vomiting, muscle cramp, fatigue and anorexia.</p>	
Memantine Hydrochloride	<p>Most common are dizziness, headache, confusion and constipation</p>	
Chemical Name BUTALBITAL USP	<p>Medical Conditions Aggravated by Exposure Hypersensitivity to material, porphyria, active alcoholism or drug dependence, liver disease, and respiratory disease.</p>	
ASPIRIN USP (80 MESH)	<p>Pre-existing alcoholism, drug abuse or dependence, asthma, especially if occurring together with other allergies and nasal polyps (history of), brain disease or head injury, colitis, convulsions (seizures), emphysema or other chronic lung disease, enlarged prostate or problems with urination, gallbladder disease or gallstones, hyperactivity, kidney disease, liver disease, diabetes mellitus (sugar diabetes), mental depression, overactive thyroid, porphyria, gout, heart disease, hemophilia or other bleeding problems, Vitamin K deficiency, stomach ulcer, especially with a history of bleeding, or other stomach problems may be aggravated by chronic overexposures to this product.</p>	
CAFFEINE USP(ANHYDROUS & PREMILLED)	<p>Hypersensitivity to material, anxiety disorders, severe cardiac disease, impaired liver function, hypertension, insomnia, or peptic ulcer.</p>	
Donepezil HCL	<p>When administered for therapeutic use, pre-existing asthma, ulcers, cardiac abnormalities, hepatic, bladder and neurological conditions may be aggravated by exposure</p>	
Memantine Hydrochloride	<p>Contraindication include hypersensitivity to any component of this product hepatic impairment</p>	

Precautionary statements

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

P280 - Wear 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

P310 - Immediately call a POISON CENTER or doctor/physician

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

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P271 - Use only outdoors or in a well-ventilated area

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

P405 - Store locked up

P501 - Dispose of contents/ container to an approved waste disposal plant

Other Information

Unknown Acute Toxicity

46% 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-%
BUTALBITAL USP	77-26-9	201-017-8	10 - 30*
TALC USP(1656)	14807-96-6	238-877-9	10 - 30*
MICROCRYSTALLINE CELLULOSE(AVICEL PH102)	9004-34-6	232-674-9	10 - 30*
CAFFEINE USP(ANHYDROUS & PREMILLED)	58-08-2	200-362-1	10 - 30*
ASPIRIN USP (80 MESH)	50-78-2	200-064-1	10 - 30*
CORN STARCH NF	9005-25-8	232-679-6	3 - 7*
Donepezil HCL	120011-70-3	N/A	1 - 5*
Memantine Hydrochloride	41100-52-1	255-219-6	0.1 - 1*
Oleic Acid	112-80-1	204-007-1	0.1 - 1*

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

4. FIRST AID MEASURES**First aid measures****General advice**

If symptoms persist, call a physician. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing.

Eye contact

Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. If symptoms persist, call a physician.

Skin Contact

Consult a physician if necessary. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation

Remove to fresh air. Call a physician. If breathing is irregular or stopped, administer artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

Ingestion

Rinse mouth. Drink plenty of water. If symptoms persist, call a physician. Do NOT induce vomiting.

Chemical Name
BUTALBITAL USP

Note to physicians

This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treatment consists primarily of management of barbiturate intoxication, reversal of the effects of codeine, and the correction of the acid-base imbalance due to salicylism. Vomiting should be induced mechanically or with emetics in the conscious patient. Gastric lavage may be used if the pharyngeal and laryngeal reflexes are present and if less than 4 hours have elapsed since ingestion. A cuffed endotracheal t.b. should be inserted before gastric lavage of the unconscious patient and when necessary to provide assisted respiration. Diuresis, alkalinization of the urine, and correction of electrolyte disturbances should be accomplished through administration of intravenous fluids such as 1% sodium bicarbonate and 5% dextrose in water. Meticulous attention should be given to maintaining adequate pulmonary ventilation. The value of vasopressor agents such as Norepinephrine or Phenylephrine Hydrochloride in treating hypotension is questionable since they increase vasoconstriction and decrease blood flow. However, if prolonged support of blood pressure is required, Norepinephrine Bitartrate (Levophed) may be given I.V. with the usual precautions and serial blood pressure monitoring. In severe cases of intoxication, peritoneal dialysis, hemodialysis, or exchange transfusion may be lifesaving. Hypoprothrombinemia should be treated with vitamin K, intravenously. Methemoglobinemia over 30% should be treated with methylene blue by slow intravenous administration. Naloxone, a narcotic antagonist, can reverse respiratory depression and coma associated with opioid overdose. Typically, a dose of 0.4 mg to 2 mg is given parenterally and may be repeated if an adequate response is not achieved. Since the duration of action of codeine may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration. A narcotic antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression. May be habit forming.

ASPIRIN USP (80 MESH)

Aspirin USP is contraindicated under the following conditions: Hypersensitivity or intolerance; patients with a hemorrhagic diathesis (e.g., hemophilia, hypoprothrombinemia, von Willebrand's disease, the thrombocytopenias, thrombasthenia, and other ill-defined hereditary platelet dysfunctions, severe vitamin K deficiency and severe liver damage); patients with the syndrome of nasal polyps, angioedema, and bronchospastic reactivity to aspirin or other nonsteroidal anti-inflammatory drugs. Anaphylactoid reactions have occurred in such patients; peptic ulcer or other serious gastrointestinal lesions; patients with porphyria.

CAFFEINE USP (ANHYDROUS & PREMILLED)

Treatment of caffeine overdose is primarily symptomatic and supportive. Caffeine levels have been shown to decrease after exchange transfusions. Convulsions may be treated with intravenous administration of diazepam or a barbiturate such as pentobarbital sodium.

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

Memantine Hydrochloride

atropine may be used as an antidote for ARICEPT overdose. Intravenous atropine sulfate titrated to effect is recommended: an initial dose of 1.0 to 2.0 mg IV with subsequent doses based upon clinical response. 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

Prevent entry into waterways, sewers, basements or confined areas. Do not flush into surface water or sanitary sewer system. 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. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

Storage Conditions

Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

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/m ³)
BUTALBITAL USP 77-26-9	N/A	N/A	N/A	100 ug/m ³
TALC USP(1656)	TWA: 2 mg/m ³ particulate	(vacated) TWA: 2 mg/m ³	IDLH: 1000 mg/m ³	N/A

14807-96-6	matter containing no asbestos and <1% crystalline silica, respirable particulate matter	respirable dust <1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more;use Quartz limit	TWA: 2 mg/m ³ containing no Asbestos and <1% Quartz respirable dust	
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) 9004-34-6	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 5 mg/m ³ (vacated) STEL: 10 mg/m ³	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust TWA: 1 mg/m ³	N/A
CAFFEINE USP(ANHYDROUS & PREMILLED) 58-08-2	N/A	N/A	N/A	250 ug/m ³
ASPIRIN USP (80 MESH) 50-78-2	TWA: 5 mg/m ³	(vacated) TWA: 5 mg/m ³	TWA: 5 mg/m ³	1778 ug/m ³
CORN STARCH NF 9005-25-8	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust	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	Capsule
Color	No information available	Odor	No information available
Odor threshold	No information available		

Property**pH****Melting point/freezing point****Boiling point / boiling range****Flash point****Evaporation rate****Flammability (solid, gas)****Flammability Limit in Air** **Upper flammability limit:** **Lower flammability limit:****Vapor pressure****Vapor density****Specific Gravity****Water solubility****Solubility in other solvents****Partition coefficient****Autoignition temperature****Decomposition temperature****Explosive properties****Oxidizing properties****Values**

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

Other Information**Molecular weight****VOC Content (%)****Density****Bulk density**

No information available

No information available

No information available

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
BUTALBITAL USP	Inhalation of airborne dusts generated by this product	May cause irritation. Flush with copious quantities of	May cause irritation. Avoid contact. Flush with copious	May cause irritation, slightly bitter taste, and toxicity.

	may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.	water.	quantities of water.	Avoid ingestion. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract.
CAFFEINE USP (ANHYDROUS & PREMILLED)	See Symptoms for more information.	Contact with eyes may cause irritation.	See Symptoms for more information.	See Symptoms for more information.
ASPIRIN USP (80 MESH)	Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.	Contact with the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.	This material is readily absorbed through the skin and excessive amounts can cause systemic toxicity, Causes skin irritation.	Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include light-headedness, dizziness, sedation, shortness of breath, nausea, vomiting, abdominal pain, and intoxicated feeling. Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced.
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.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
MICROCRYSTALLINE CELLULOSE (AVICEL PH102)	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h
CAFFEINE USP (ANHYDROUS & PREMILLED)	= 192 mg/kg (Rat)	N/A	N/A
ASPIRIN USP (80 MESH)	= 200 mg/kg (Rat)	N/A	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
BUTALBITAL USP	No adequate studies have been conducted in animals to determine whether this medication has the potential for carcinogenesis, mutagenesis, or impairment of fertility.	No information available.	No congenital abnormalities were uncovered in 112 pregnancies that included first trimester exposure to butalbital. One case report has described severe neonatal withdrawal that began within 2 days of birth in a male infant whose mother took 150 mg butalbital daily during the last 2 months of pregnancy. The barbiturate had been prescribed in a fixed-combination headache medication. The neonatal symptoms of barbiturate withdrawal were characterized as including over-activity, irritability, vasomotor instability and	This medication is excreted in breast milk in small amounts, but the significance of their effects on nursing infants is unknown. Because of the potential for serious adverse reaction in nursing infants from this medication, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

			<p>tremulousness. After long-term maternal barbiturate therapy, a vitamin K-responsive bleeding abnormality may also occur in the neonate. Although there are few reports concerning butalbital specifically, teratogenic effects have been associated with use of barbiturates in general. Because use of butalbital does not represent a medical necessity, use of butalbital during pregnancy is not recommended.</p>	
<p>CAFFEINE USP(ANHYDROUS & PREMILLED)</p>	<p>Caffeine (as caffeine base) increased the sister chromatid exchange (SCE) SCE/cell metaphase (exposure time dependent) in an in vivo mouse metaphase analysis. Caffeine also potentiated the genotoxicity of known mutagens and enhanced the micronuclei formation (5-fold) in folate-deficient mice. However, caffeine did not increase chromosomal aberrations in in vitro Chinese hamster ovary cell (CHO) and human lymphocyte assays and was not mutagenic in an in vitro CHO/hypoxanthine guanine phosphoribosyltransferase (HGPRT) gene mutation assay, except at cytotoxic concentrations. In addition, caffeine was not clastogenic in an in vivo mouse micronucleus assay.</p>	<p>In a 2-year study in Sprague-Dawley rats, caffeine (as caffeine base) administered in drinking water was not carcinogenic in male rats at doses up to 102 mg/kg or in female rats at doses up to 170 mg/kg (approximately 2 and 4 times, respectively, the maximum recommended intravenous loading dose for infants on a mg/m2 basis). In an 18-month study in C57BL/6 mice, no evidence of tumorigenicity was seen at dietary doses up to 55 mg/kg (less than the maximum recommended intravenous loading dose for infants on a mg/m2 basis).</p>	<p>This study evaluated the timing and amount of caffeine intake by women and men undergoing in vitro fertilization/ IVF and gamete intra-Fallopian transfer (GIFT) on oocyte retrieval, sperm parameters, fertilization, multiple gestations, miscarriage, and live births. A prospective study of 221 couples was conducted in Southern California between 1993 and 1998. `Usual' caffeine intake during lifetime and 1 year prior to attempt, caffeine intake during the week of the initial clinic visit, as well as intake during the week of the procedure, was evaluated from beverages (coffee, soda, tea) and chocolates. Not achieving a live birth was significantly associated with `usual' female caffeine consumption [adjusted odds ratios (95% confidence intervals): 3.1 (1.1, 9.7) and 3.9 (1.3, 11.6) for intake of >2-50 and 50 mg/day, compared with 0-2 mg/day] and consumption during the week of the initial visit [2.9 (1.1, 7.5) and 3.8 (1.4, 10.7)] female compared with 0-2 mg/day, although caffeine use was low. Infant gestational age decreased by 3.8 (-6.9, -0.7) or 3.5 (-6.7, -0.3) weeks for women who consumed >50 mg/day of caffeine `usually' or during the week of the initial visit. The odds of having multiple gestations increased by 2.2 (1.1, 4.4) and 3.0 (1.2, 7.4) for men who increased their `usual' intake or intake during the week of the initial visit by an extra 100 mg/day. Caffeine intake was not significantly associated with</p>	<p>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.</p>

			<p>other outcomes. This is the first IVF/GIFT study to report any effect of caffeine on live births, gestational age, and multiple gestations. If these findings are replicated, caffeine use should be minimized prior to and while undergoing IVF/GIFT.</p> <p>Concern for the teratogenicity of caffeine is not relevant when administered to infants. In studies performed in adult animals, caffeine (as caffeine base) administered to pregnant mice as sustained release pellets at 50 mg/kg (less than the maximum recommended intravenous loading dose for infants on a mg/m2 basis), during the period of organogenesis, caused a low incidence of cleft palate and exencephaly in the fetuses. There are no adequate and well-controlled studies in pregnant women.</p>	
ASPIRIN USP (80 MESH)	No information available.	Not suspected of being a human carcinogen.	None known.	It is not known whether this drug is excreted in human milk. Because most drugs are excreted in human milk, if use of this drug is deemed essential, the patient should stop nursing.
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
BUTALBITAL USP	<p>Butalbital may impair mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. Alcohol and other CNS depressants may produce an additive CNS depression. Butalbital may be habit-forming and is a Schedule III controlled substance.</p>	No information available.

Chronic toxicity

May cause adverse effects on the bone marrow and blood-forming system. May cause adverse liver effects.

Target Organ Effects

blood, Central nervous system, Central Vascular System (CVS), Eyes, Gastrointestinal tract (GI), kidney, liver, Respiratory system, Skin, Urinary Tract, Musculo-skeletal system.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 46% 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) 349 mg/kg
ATEmix (dermal) 6930 mg/kg
ATEmix (inhalation-dust/mist) 20.9 mg/l

12. ECOLOGICAL INFORMATION

Ecotoxicity

51.7% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
TALC USP(1656) 14807-96-6	N/A	100: 96 h Brachydanio rerio g/L LC50 semi-static	N/A
CAFFEINE USP(ANHYDROUS & PREMILLED) 58-08-2	N/A	151: 96 h Pimephales promelas mg/L LC50 flow-through	182.12: 4 h Daphnia species mg/L EC50
ASPIRIN USP (80 MESH) 50-78-2	N/A	N/A	100: 48 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
BUTALBITAL USP 77-26-9	None known	Based on the BCF, the potential for bioaccumulation in aquatic organisms is low.	Mobility in soil High	1.87 (est)
CAFFEINE USP(ANHYDROUS & PREMILLED) 58-08-2	No information available	Low	Low mobility in soil	log Kow = -0.07
ASPIRIN USP (80 MESH) 50-78-2	No information available	No information available	High Mobility in soil	1.19
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
TALC USP(1656) 14807-96-6	-	Group 3	-	X
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) 9004-34-6	-	Group 1	Known	X
CAFFEINE USP(ANHYDROUS & PREMILLED) 58-08-2	-	Group 3	-	-

*IARC (International Agency for Research on Cancer)
 Group 1 - Carcinogenic to Humans
 Not classifiable as a human carcinogen
 NTP (National Toxicology Program)
 Known - Known Carcinogen
 OSHA (Occupational Safety and Health Administration of the US Department of Labor)
 X - Present*

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 Yes
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 contains the following Proposition 65 chemicals

Chemical Name	California Proposition 65
BUTALBITAL USP - 77-26-9	Developmental
MICROCRYSTALLINE CELLULO(AVICEL PH102) - 9004-34-6	Carcinogen
ASPIRIN USP (80 MESH) - 50-78-2	Developmental Female Reproductive

U.S. State Right-to-Know Regulations

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

16. OTHER INFORMATION

Revision Date 16-Jul-2019
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