

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Product name: Donnatal® Elixir Grape Flavored
Product Code(s): Donnatal® Elixir Grape Flavored
Synonym(s): Active ingredients - Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Donnatal® Elixir is indicated for use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. It may also be useful as adjunctive therapy in the treatment of duodenal ulcer.
Restrictions on use: Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

1.3 Details of the supplier and of the safety data sheet

Distributed by
 VistaPharm, Inc.
 7265 Ulmerton Road
 Largo, FL 33771 USA
 +1-877-437-8567

1.4 Emergency telephone number

In the continental USA: +1-877-437-8567

SECTION 2 - HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

Product definition: Mixture
Classification in accordance with 29 CFR 1910 (OSHA HCS) and Regulation (EC) No 1272/2008
 Not a dangerous substance according to OSHA or to European Union Legislation

2.2 Label elements

Not a dangerous substance according to GHS

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Percentage	Ingredient	CAS Number	EC Number	Index Number	GHS Classification
0.28	Phenobarbital	50-06-6	200-07-0	-----	H301, H317, H351, H360
<0.01	Hyoscyamine Sulfate	6835-16-1	-----	-----	-----
<0.01	Atropine Sulfate	55908-99-6	-----	-----	-----
<0.01	Scopolamine Hydrobromide	6533-68-2	-----	-----	-----

Inactive ingredients: Purified Water; Glycerin; Sorbitol; Ethyl Alcohol; Sucrose; Saccharin Sodium; Artificial and Natural Grape Flavor; FD&C Red #3; FD&C Blue #1

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

SECTION 4 - FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation: If product mist or vapor causes respiratory irritation or distress, move the exposed person to fresh air immediately. If breathing is difficult or irregular, administer oxygen; if respiratory arrest occurs, start artificial respiration by trained personnel. Get immediate medical attention. If unconscious place in the recovery position and get immediate medical attention. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. Ensure that medical personnel are aware of the material involved. If respiratory irritation persists or if other symptoms develop, seek medical attention.

Eyes: Immediately flush eyes with large amounts of water for 15 minutes, occasionally lifting the upper and lower eyelids. Remove contact lenses after the first 2 minutes and continue rinsing. If irritation persists seek medical attention, preferably from an ophthalmologist.

Skin: Rinse skin with water while removing contaminated clothing. Wash affected area with soap and water. Wash contaminated clothing and shoes thoroughly before reuse. In the event of any complaints or symptoms, avoid further exposure and seek medical attention.

Ingestion: Rinse mouth with water if the victim is conscious. Remove dentures, if present. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept lower than the waist so that vomit does not enter into the lungs. Never give anything by mouth to an unconscious or convulsing person. Do not leave the victim unattended. If the victim is unconscious, place in the recovery position and get immediate medical attention. Immediately contact a Poison Control Center or doctor. Seek medical attention if adverse health effects persist or are severe.

4.2 Most important symptoms and effects, both acute and delayed

Potential health symptoms and effects

Eyes: May cause mild, transient eye irritation.

Skin: May cause mild, transient skin irritation.

Inhalation: Low inhalation hazard with recommended use and handling. Vapor or mist may cause irritation of the upper respiratory tract.

Ingestion: May cause gastrointestinal upset with dry mouth, nausea, vomiting, bloating, diarrhea and constipation. May cause central nervous system effects, such as headache, blurred vision, mydriasis (pupil dilation), loss of sense of taste, nervousness, drowsiness, dizziness, weakness and insomnia. May cause musculoskeletal pain, palpitations and tachycardia. Ingestion of large amounts may result in fatal respiratory arrest or coma. May cause urinary hesitancy and retention. May cause impotence and suppression of lactation. May cause severe allergic reactions including anaphylaxis in susceptible individuals.

Phenobarbital can be abused resulting in dependence (addiction) and withdrawal symptoms. Refer to the product insert for complete side effect data.

Chronic: Phenobarbital may be habit forming. May cause damage to the unborn child. Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

4.3 Indication of any immediate medical attention and special treatment needed

Advice to doctor and hospital personnel

The signs and symptoms of overdose are headache, nausea, vomiting, blurred vision, dilated pupils, hot and dry skin, dizziness, dryness of the mouth, difficulty in swallowing and CNS stimulation. Treatment should consist of gastric lavage, emetics and activated charcoal. If indicated, parenteral cholinergic agents such as physostigmine or bethanechol chloride should be used.

Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

SECTION 5 - FIRE FIGHTING MEASURES

5.1 Extinguishable media

Suitable methods of extinction: Use extinguishing media suitable for the surrounding fire.

Unsuitable methods of extinction: None known

5.2 Special hazards arising from the substance or mixture

During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent or may be delayed. Obtain medical attention.

5.3 Advice for firefighters

Full protective equipment including self-contained breathing apparatus should be used. If possible, firefighters should control runoff water contaminated with this material and prevent it from being discharged to any waterway, sewer or drain to prevent environmental contamination.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Evacuate non-essential personnel from the area. Wear appropriate protective clothing designated in Section 8.2. Remove all sources of ignition. No smoking. Ventilate the area. Clean up spills immediately. Spill creates a slip hazard.

6.2 Environmental precautions

Avoid dispersal of spilled material or runoff and prevent contact with soil and entry into drains, sewers and waterways.

6.3 Methods and materials for containment and cleaning up

Cover drains and contain spill. Small spills can be wiped up with absorbent material (e.g. cloth, fleece). Cover larger spills with inert absorbent. Do not use combustible material such as sawdust. Collect material and place into an approved, labeled container for proper disposal. Observe possible material restrictions (Sections 7.2 and 10.5). Dispose of material via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations. Clean contaminated area with soap and water.

6.4 Reference to other sections

For symptoms of overexposure and first aid treatment, see Section 4.

SECTION 7 - HANDLING AND STORAGE

7.1 Precautions for safe handling

Observe label precautions. Wear all appropriate protective equipment specified in Section 8.2. Do not get in eyes or on skin or clothing. No smoking. If normal use presents a respiratory hazard, use only adequate ventilation or wear an appropriate respirator.

Advice on protection against fire and explosion

Not expected to be a fire or explosion hazard

7.2 Conditions for safe storage, including any incompatibilities

Store at 20 - 25 °C (68 - 77 °F) in a dry, well-ventilated area away from incompatible materials (see Section 10.5), food and drink. Keep container tightly closed when not in use. Protect containers from physical damage. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Containers of this material are hazardous when empty as they contain product residues. Use appropriate containment to avoid environmental contamination. Ventilate closed areas. Keep locked up and out of reach of children.

7.3 Specific end uses

Apart from the uses mentioned in Section 1.2, no other specific uses are stipulated.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure values.

8.2 Exposure controls

Engineering Measures: Use adequate ventilation. Local exhaust is preferable. Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. Refer to Section 7.1.

Individual protection measures: Not normally required. Wear protective clothing to prevent repeated or prolonged contact with product. Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled.

Hygiene measures: Facilities storing or using this material should be equipped with an eyewash station and safety shower. Change contaminated clothing. Wash hands and forearms thoroughly after use, before eating, drinking, smoking or using the lavatory.

Eye/face protection: None normally required. If there is a danger of splashing wear safety glasses with unperforated side shields during use.

Hand Protection: Not normally needed. For prolonged or repeated skin contact wear gloves recommended by supplier for protection against materials in Section 3. Breakthrough time of selected gloves must be greater than the intended use period.

Other protective equipment: Not normally needed. Wear protective clothing and protective boots if the situation requires.

Respiratory Protection: No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to vapor/fume at levels exceeding the exposure limits.

Environmental exposure controls: Do not empty into drains.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Clear purple liquid
Odor	Grape
Odor Threshold	No data available
Molecular Weight	232.24 g/mol (Phenobarbital)
Chemical Formula	C ₁₂ H ₁₂ N ₂ O ₃ (Phenobarbital)
pH	4.5 - 5.5
Freezing/Melting Point, Range	No data available
Initial Boiling Point	No data available
Evaporation Rate	No data available
Flammability (solid, gas)	Not applicable
Flash Point	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Lower Explosive Limit (LEL)	No data available
Upper Explosive Limit (UEL)	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.05 - 1.29 @ 25 °C
Viscosity	15 cPs @ 25 °C
Solubility in Water	Miscible
Partition Coefficient: n-octanol/water	No data available
Volatiles by Weight @ 21° C	No data available

9.2 Other data

No relevant additional information available

SECTION 10 - STABILITY AND REACTIVITY

10.1 Reactivity

Product is stable under normal handling and use.

10.2 Chemical stability

Product is stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid temperature extremes.

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

Thermal decomposition products include oxides of carbon, oxides of nitrogen.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute oral toxicity

May be harmful if swallowed in large quantities.

Acute inhalation toxicity

Expected to have low acute inhalation toxicity

Acute dermal toxicity

Expected to have low acute dermal toxicity

Skin irritation

May cause skin irritation.

Eye irritation

May cause eye irritation.

Sensitization

Severe allergic reactions, including anaphylaxis, urticaria and other dermal manifestations, may occur. Refer to product insert for full details.

Genotoxicity

No data available

Germ cell Mutagenicity

No data available

Specific organ toxicity - single exposure

No data available

Specific organ toxicity - repeated exposure

Refer to product insert for full details.

Aspiration hazard

No data available

11.2 Further information

Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Overdosage of barbiturates produces CNS depression ranging from sleep to profound coma to death. May cause respiratory depression, central hypoventilation and cyanosis. May cause cold, clammy skin, fever, tachycardia, hypotension and decreased urine formation. Pupils are usually slightly constricted but may be dilated in severe poisoning. Patients with severe overdosage often experience typical shock syndrome. Apnea, circulatory collapse, respiratory arrest and death may occur. Complications such as pneumonia, pulmonary edema or renal failure may also prove fatal. Other complications which may occur are congestive heart failure, cardiac arrhythmias and urinary tract infections. Some patients have developed bullous cutaneous lesions which heal slowly.

Phenobarbital may be habit forming. Tolerance and psychological and physical dependence may occur with continued use. Phenobarbital, a barbiturate, can cause fetal damage. Barbiturates readily cross the placental barrier and are distributed throughout fetal tissues; the highest concentrations are found in the placenta, fetal liver and brain.

Ethanol (CAS #64-17-5): Carcinogen classifications of IARC, ACGIH, NTP, OSHA and California Proposition 65 apply to *beverage use only*. This product is NOT intended for this use. Ethanol has been shown to produce fetotoxicity in the embryo or fetus of laboratory animals. Prenatal exposure to ethanol is associated with congenital malformations that have collectively been termed "fetal alcohol syndrome".

No conclusive data is available regarding the mutagenicity or teratogenicity of this product in humans, nor is there any available data that indicates that it causes adverse developmental or fertility effects.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12 - ECOLOGICAL INFORMATION**12.1 Toxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulation potential

This product is not expected to bioaccumulate.

12.4 Mobility in soil

This product is expected to be mobile in soil.

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects**Additional ecological information**

Do not allow material to enter into surface waters, wastewater or soil.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

SECTION 13 - DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Methods of disposal: The generation of waste should be avoided or minimized whenever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

RCRA P-Series: No listing

RCRA U-Series: No listing

SECTION 14 - TRANSPORT INFORMATION

Note: Transportation information provided is for reference only. Customer is urged to consult 49 CFR 100 - 177, IMDG, IATA, EC, United Nations TDG and WHMIS (Canada) TDG information manuals for detailed regulations and exceptions covering specific container sizes, packaging materials and methods of shipping.

NOT REGULATED FOR TRANSPORT

SECTION 15 - REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for substance or mixture

U. S. Federal Regulations

OSHA Hazard Communication Standard: This material is not classified as hazardous in accordance with OSHA 29 CFR 1910.1200.

TSCA Status: Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate and Scopolamine Hydrobromide are not listed on the Toxic Substance Control Act Inventory (TSCA) as they are intended for use in applications regulated by the Food and Drug Administration in the United States. This product can only be used for TSCA exempt purposes such as R&D or drug use. It is not subject to TSCA 12(b) Export Notification.

DEA Schedule IV (29 CFR 1308.14): Phenobarbital (CAS #50-06-6) is a controlled substance.

Superfund Amendments and Reauthorization Act (SARA)

SARA Section 311/312 Hazard Categories: None known

SARA 313 Information: None of the chemicals in this product exceed the threshold (de minimis) reporting levels established by Section 313 of the Emergency Planning and Community Right-to Know Act of 1986.

SARA 302/304 Extremely Hazardous Substance: No components of the product are subject to the reporting requirements of these sections of Title III of SARA.

SARA 302/304 Emergency Planning & Notification: No components of the product are subject to the reporting requirements of these sections of Title III of SARA.

Comprehensive Response Compensation and Liability Act (CERCLA): No components of the product exceed the threshold (de minimis) reporting levels for hazardous wastes established by CERCLA.

Clean Air Act (CAA)

This product does not contain any chemicals listed as a Hazardous Air Pollutant (HAP) designated in CAA Section 112 (b).

This product does not contain any Class 1 Ozone depleters.

This product does not contain any Class 2 Ozone depleters.

Clean Water Act (CWA)

None of the chemicals in this product are listed as Hazardous Substances under the CWA.

None of the chemicals in this product are listed as Priority Pollutants under the CWA.

None of the chemicals in this product are listed as Toxic Pollutants under the CWA.

U.S. State Regulations

California Prop 65, Safe Drinking Water and Toxic Enforcement Act of 1986

Carcinogen classification for Ethanol (CAS #64-17-5) applies to *beverage use only*. This product is NOT intended for this use.

Other U.S. State Inventories

Ethanol (CAS #64-17-5) is listed on the following the State Hazardous Substance Inventories, Right-to-Know lists and/or Air Quality/Air Pollutants lists: CA, ID, MA, MN, NJ, PA, RI, WA.

Canada

WHMIS Hazard Symbol and Classification: Uncontrolled product according to WHMIS classification criteria

Canadian National Pollutant Release Inventory (NPRI): None of the components of this product are not listed on the NPRI.

European Economic Community

WGK, Germany (Water danger/protection): No data available

Global Chemical Inventory Lists

Country	Inventory Name	Inventory Listing*
Canada	Domestic Substance List (DSL)	No
Canada	Non-Domestic Substance List (NDSL)	No
Europe	Inventory of New and Existing Chemicals (EINECS)	No
United States	Toxic Substance Control Act (TSCA)	No
Australia	Australian Inventory of Chemical Substances (AICS)	No
New Zealand	New Zealand Inventory of Chemicals (NZIoC)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
Philippines	Philippines Inventory of Chemicals and Chemical Substances (PICCS)	No

*Yes - All components of this product are in compliance with the inventory requirements administered by the governing country.

No - One or more components of this product are not on the inventory or are exempt from listing.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16 - OTHER INFORMATION

Hazardous Material Information System (HMIS)

Health	<input type="checkbox"/> 1
Flammability	<input type="checkbox"/> 1
Physical Hazard	<input type="checkbox"/> 1
Personal Protection	<input type="checkbox"/>

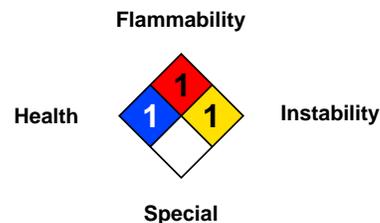
HMIS Hazard Rating Legend

0 = Minimal 1 = Slight 2 = Moderate 3 = Serious
4 = Severe * = Chronic Health Hazard

NFPA Hazard Rating Legend

0 = Insignificant 1 = Slight 2 = Moderate
3 = High 4 = Extreme

National Fire Protection Association (NFPA)



Full text of GHS Hazard Phrases referenced in Section 3 (not covered in Section 2)

H301 - Toxic if swallowed

H317 - May cause an allergic skin reaction

H351 - Suspected of causing cancer

H360 - May damage fertility or the unborn child

The information herein is given in good faith and is believed to be accurate and correct; however, no warranty, expressed or implied, is made. VistaPharm, Inc assumes no responsibility for personal injury or property damage that may arise from the use of this material since the conditions of handling and use are beyond our control. It is the responsibility of the user to comply with all Federal, State and local laws and regulations regarding use of this product. Vendees or users assume all risks associated with the use of this material.

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