



# 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** URSODIOL 500MG TABS BULK

### Other means of identification

**Product Code** 325799

**Synonyms** Actigall, Arsacol, Cholit-ursan, Delursan, Destolit, Deursil, Litursol, Lyeton, Peptarom, Solutrat, Ursacol, UrSO, Ursobilin, Ursochol, Ursodamor; Ursodeoxycholic Acid

### Recommended use of the chemical and restrictions on use

**Recommended Use** Ursodiol suppresses hepatic synthesis and secretion of cholesterol, and inhibits intestinal absorption of cholesterol.

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 not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

### Label elements

#### **Emergency Overview**

The product contains no substances which at their given concentration, are considered to be hazardous to health

**Appearance** Tablet

**Physical state** Solid

**Odor** No information available

**Chemical Name**  
Ursodiol USP, micronized

**Symptoms**  
Symptoms during therapeutic use may include headache, nausea and dizziness. Other lesser reported symptoms include abdominal irritation and discomfort, diarrhea, gas,

	vomiting (diarrhea has been associated with overdose), joint and muscle aches and pain, back pain, and upper respiratory, nose and throat irritation, inflammation and infection; allergic or sensitization reactions are reported with pure material. Rare cases of skin eruptions have been reported.
<b>POVIDONE USP(PLASDONE K-29-32)</b>	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.
<b>Chemical Name</b>	<b>Medical Conditions Aggravated by Exposure</b>
<b>Ursodiol USP, micronized</b>	Patients with complete biliary obstruction and known hypersensitivity or intolerance to ursodiol or any of the components of the formulation.
<b>POVIDONE USP(PLASDONE K-29-32)</b>	Known hypersensitivity to this medication

**Other Information**

Unknown Acute Toxicity

24.9% 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-%
Ursodiol USP, micronized	128-13-2	204-879-3	15 - 40*
PURIFIED WATER USP	7732-18-5	231-791-2	10 - 30*
MICROCRYSTALLINE CELLULOSE(AVICEL PH102)	9004-34-6	232-674-9	10 - 30*
SODIUM STARCH GLYCOLATE(GLYCOLYS)	6833-40-9	N/A	1 - 5*
Aquarius Preferred WhiteHSP BPP218011	EZ99-02-76	N/A	1 - 5*
POVIDONE USP(PLASDONE K-29-32)	9003-39-8	N/A	1 - 5*
Tropium Chloride	10405-02-4	233-875-4	<0.1*
Titanium Dioxide	1317-70-0	215-280-1	<0.1*
LACTOSE MONOHYDRATE NF(FAST FLOW)(SPRAY DRIED)	64044-51-5	N/A	<0.1*
MAGNESIUM STEARATE NF(VEGETABLE SOURCE)	557-04-0	209-150-3	<0.1*
TALC USP(1656)	14807-96-6	238-877-9	<0.1*
Sucrose Palmitate	26446-38-8	247-706-7	<0.1*
STEARIC ACID NF	57-11-4	200-313-4	<0.1*
PWDRD CELLULOSE BW40 NF	9004-32-4	N/A	<0.1*
FERRIC OXIDE NF (RED 30)	1309-37-1	215-168-2	<0.1*
CROSCARMELLOSE SODIUM NF(TYPE A, AC-DI-SOL)	74811-65-7	N/A	<0.1*
COLOIDAL SILICON DIOXIDE(CAB-O-SIL GRADE M-5P)	112945-52-5	N/A	<0.1*
POLYETHYLENE GLYCOL NF6000	25833-68-3	N/A	<0.1*
CORN STARCH NF	9005-25-8	232-679-6	<0.1*
White Cresin Wax	8002-74-2	232-315-6	<0.1*
CARNABUA WAX NF	8015-86-9	232-399-4	<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.

## 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/m <sup>3</sup> )
Ursodiol USP, micronized 128-13-2	N/A	N/A	N/A	800 ug/m <sup>3</sup>
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) 9004-34-6	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust TWA: 1 mg/m <sup>3</sup>	N/A

		(vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 5 mg/m <sup>3</sup> (vacated) STEL: 10 mg/m <sup>3</sup>		
Tropium Chloride 10405-02-4	N/A	N/A	N/A	100 ug/m <sup>3</sup>
MAGNESIUM STEARATE NF(VEGETABLE SOURCE) 557-04-0	TWA: 10 mg/m <sup>3</sup> inhalable particulate matter TWA: 3 mg/m <sup>3</sup> respirable particulate matter TWA: 10 mg/m <sup>3</sup> inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m <sup>3</sup> respirable particulate matter except stearates of toxic metals	N/A	N/A	N/A
TALC USP(1656) 14807-96-6	TWA: 2 mg/m <sup>3</sup> particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter	(vacated) TWA: 2 mg/m <sup>3</sup> respirable dust <1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more;use Quartz limit	IDLH: 1000 mg/m <sup>3</sup> TWA: 2 mg/m <sup>3</sup> containing no Asbestos and <1% Quartz respirable dust	N/A
STEARIC ACID NF 57-11-4	TWA: 10 mg/m <sup>3</sup> inhalable particulate matter TWA: 3 mg/m <sup>3</sup> respirable particulate matter	N/A	N/A	N/A
FERRIC OXIDE NF (RED 30) 1309-37-1	TWA: 5 mg/m <sup>3</sup> respirable particulate matter	TWA: 10 mg/m <sup>3</sup> fume TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 10 mg/m <sup>3</sup> fume and total dust Iron oxide (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction regulated under Rouge	IDLH: 2500 mg/m <sup>3</sup> Fe dust and fume TWA: 5 mg/m <sup>3</sup> Fe dust and fume	N/A
CORN STARCH NF 9005-25-8	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust	N/A
White Cresin Wax 8002-74-2	TWA: 2 mg/m <sup>3</sup> fume	(vacated) TWA: 2 mg/m <sup>3</sup>	TWA: 2 mg/m <sup>3</sup> fume	N/A

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.

<b>Skin and body protection</b>	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.).
<b>Respiratory protection</b>	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

<b>Physical state</b>	Solid	<b>Appearance</b>	Tablet
<b>Color</b>	No information available	<b>Odor</b>	No information available
<b>Odor threshold</b>	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
Ursodiol USP, micronized	See Symptoms for more information.	May cause irritation.	May cause irritation.	May cause gastrointestinal tract irritation with hypermotility and diarrhea. It may affect the behavior/central nervous system (convulsions, somnolence). Prolonged or repeated ingestion may affect the liver (hepatitis, hepatocellular necrosis), blood, urinary system, and metabolism (weight loss).
Tropium 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 Tropium. 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.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Ursodiol USP, micronized	= 4600 mg/kg ( Rat )	N/A	N/A
PURIFIED WATER USP	> 90 mL/kg ( Rat )	N/A	N/A
MICROCRYSTALLINE CELLULOSE(AVICEL PH102)	> 5 g/kg ( Rat )	> 2 g/kg ( Rabbit )	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h
POVIDONE USP(PLASDONE K-29-32)	= 100 g/kg ( Rat )	N/A	N/A
Tropium 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 <sup>3</sup> ( 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

**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
Ursodiol USP, micronized	not genotoxic in the Ames test, the mouse lymphomacell forward mutation test, the human lymphocyte sister chromatid exchange test, the mouse spermatogonia chromosome aberration test, the Chinese hamster micronucleus test	Two year studies in mice and rats at doses of 3.2-5.4 times therecommended maximum clinical dose of 15 mg/kg/day (555mg/m2/day) did not show evidence of carcinogenicity. Ursodiol produced a significantly (p<0.5, Fisher's exacttest)	Reproduction studies have been performed in pregnant rats at oral doses up to 22 times the recommended maximum human dose (based on body surface area)and in pregnant rabbits at oral doses up to 7 times the recommended maximum	No information available

	and the Chinese hamster bone marrow cell chromosome aberration test.	increased incidence of pheochromocytomas of the adrenalmedulla in females of the highest dose group. .On theother hand, in a 32-week rat study, ursodiol at a daily dose of 240mg/kg (1,440 mg/m2, 2.6 times the maximum recommended humandose based on body surface area) suppressed the colonic carcinogeniceffect of another known carcinogen azoxymethane.	human dose (based on body surface area) and have revealed no evidence of impaired fertility or harm to the fetus due to ursodiol.	
POVIDONE USP(PLASDONE K-29-32)	No information available.	Not suspected of being a human carcinogen.	No information available.	No information available
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.

**Target Organ Effects** Eyes, Gastrointestinal tract (GI), Respiratory system, Skin.

#### Numerical measures of toxicity - Product Information

**Unknown Acute Toxicity** 24.9% of the mixture consists of ingredient(s) of unknown toxicity

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

<b>ATEmix (oral)</b>	6977 mg/kg
<b>ATEmix (dermal)</b>	9288 mg/kg
<b>ATEmix (inhalation-dust/mist)</b>	26.9 mg/l

## 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

77.47% of the mixture consists of component(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

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Ursodiol USP, micronized 128-13-2	N/A	N/A	N/A	3
Trospium Chloride 10405-02-4	No information available	No information available	No information available	Log P = 0.70

**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

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>ICAO (air)</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	Not regulated

## 15. REGULATORY INFORMATION

### International Inventories

<b>TSCA</b>	Not Listed
<b>DSL/NDSL</b>	Not Listed
<b>EINECS/ELINCS</b>	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 CELLULOSE (AVICEL PH102) 9004-34-6	-	Group 1	Known	X
POVIDONE USP (PLASDONE K-29-32) 9003-39-8	-	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**

<b>Acute health hazard</b>	Yes
<b>Chronic Health Hazard</b>	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

**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**