SAFETY DATA SHEET

ADVOCIN (danofloxacin mesylate) Injectable Solution

Section 1. Identification

GHS product identifier : ADVOCIN (danofloxacin mesylate) Injectable Solution

Product type : Liquid.

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

Identified uses

Not applicable.

Uses advised against
Not for human use

Supplier's details : Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)
1-866-531-8896
1-888-963-8471

Emergency telephone number (with hours of operation) : CHEMTREC (24 hours): 1-800-424-9300
International CHEMTREC (24 hours): +1-703-527-3887

Company Name (EU): Zoetis Belgium S.A.
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium
Telephone: +32 10 808080

Rocky Mountain Poison and Drug Center: 1-866-531-8896
Product Support/Technical Services: 1-888-963-8471

Contact E-Mail: VMIPSrecords@zoetis.com

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : ACUTE TOXICITY (oral) - Category 4
AQUATIC HAZARD (ACUTE) - Category 2

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : Harmful if swallowed.
Toxic to aquatic life.

Precautionary statements

Prevention : Avoid release to the environment. Do not eat, drink or smoke when using this product. Wash thoroughly after handling.

Response : IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. Rinse mouth.

Storage : Not applicable.

Section 2. Hazards identification

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	Identifiers
2-pyrrolidone	≥10 - <25	CAS: 616-45-5
magnesium oxide	≤3	CAS: 1309-48-4
phenol	<0.1	CAS: 108-95-2

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

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

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Not applicable.

Indication of immediate medical attention and special treatment needed, if necessary

In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

No specific treatment.

Section 4. First aid measures

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst. This material is toxic to aquatic life. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

Hazardous thermal decomposition products : Decomposition products may include the following materials:, carbon dioxide, carbon monoxide, nitrogen oxides, metal oxide/oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : Keep unnecessary personnel away.

For emergency responders : Keep unnecessary personnel away. If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

Methods and materials for containment and cleaning up

Small spill : Stop leak if without risk. Move containers from spill area. Absorb with an inert material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid release to the environment. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
magnesium oxide	**CAL OSHA PEL (United States, 5/2018)** TWA 8 hours: 10 mg/m³ (as Mg). **OSHA PEL (United States, 5/2018)** TWA 8 hours: 15 mg/m³. Form: Total particulates. **OSHA PEL 1989 (United States, 3/1989)** TWA 8 hours: 10 mg/m³. Form: Total particulates. **ACGIH TLV (United States, 1/2024)** A4. TWA 8 hours: 10 mg/m³. Form: Inhalable fraction.
phenol	**NIOSH REL (United States, 10/2020)** Absorbed through skin. TWA 10 hours: 5 ppm. TWA 10 hours: 19 mg/m³. CEIL 15 minutes: 15.6 ppm. CEIL 15 minutes: 60 mg/m³. **CAL OSHA PEL (United States, 5/2018)** Absorbed through skin. TWA 8 hours: 19 mg/m³. TWA 8 hours: 5 ppm. **OSHA PEL (United States, 5/2018)** Absorbed through skin. TWA 8 hours: 5 ppm. TWA 8 hours: 19 mg/m³. **OSHA PEL 1989 (United States, 3/1989)** Absorbed through skin. TWA 8 hours: 5 ppm. TWA 8 hours: 19 mg/m³. **ACGIH TLV (United States, 1/2024)** A4. Absorbed through skin. TWA 8 hours: 5 ppm. TWA 8 hours: 19 mg/m³.

Section 8. Exposure controls/personal protection

Biological exposure indices

Ingredient name	Exposure indices
phenol	**ACGIH BEI (United States, 1/2024)** BEI: 250 mg/g creatinine, phenol [in urine]. Sampling time: end of shift.

Control Banding Approach

Not available.

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties and safety characteristics

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

Physical state : Liquid. [Sterile solution]

Color : Colorless.

Odor : Not available.

Section 9. Physical and chemical properties and safety characteristics

Odor threshold : Not available.

pH : Not available.

Melting point/freezing point : Not available.

Boiling point or initial boiling point and boiling range : Not available.

Flash point : Not available.

Evaporation rate : Not available.

Flammability : Not available.

Lower and upper explosion limit/flammability limit : Not available.

Vapor pressure : Not available.

Relative vapor density : Not available.

Relative density : Not available.

Solubility in water : Not available.

Partition coefficient: n-octanol/water : Not applicable.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Dynamic (room temperature): Not available.
Kinematic (room temperature): Not available.
Kinematic (40°C (104°F)): Not available.

Particle characteristics

Pmax : Not available.

Kst : Not available.

Min. Ignition Temperature (Dust) : Not available.

Minimum ignition energy (MIE) - dust cloud : Not available.

Median particle size : Not applicable.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : No specific data.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result
2-pyrrolidone	**Rat - Oral - LD50** 6500 mg/kg **Rat - Oral - LD50** 328 mg/kg Toxic effects: Behavioral - Coma Lung, Thorax, or Respiration - Dyspnea
phenol	**Rat - Dermal - LD50** 669 mg/kg **Rat - Oral - LD50** 317 mg/kg **Rat - Oral - LD50** 317 mg/kg Toxic effects: Behavioral - Convulsions or effect on seizure threshold **Rat - Dermal - LD50** 669 mg/kg Toxic effects: Behavioral - Tremor Kidney, Ureter, and Bladder - Hematuria Skin After topical exposure - Cutaneous sensitization (experimental) **Rabbit - Dermal - LD50** 630 mg/kg **Rat - Inhalation - LC50 Vapor** 316 mg/m³ [4 hours]

Conclusion/Summary [Product] : Harmful if swallowed.

Skin corrosion/irritation

Product/ingredient name	Result
phenol	**Pig - Skin - Severe irritant** Duration of treatment/exposure: 0.5 minutes Amount/concentration applied: 400 uL **Rabbit - Skin - Mild irritant** Amount/concentration applied: 100 mg **Rabbit - Skin - Severe irritant** Amount/concentration applied: 535 mg

Conclusion/Summary [Product] : Not applicable.

Serious eye damage/eye irritation

Product/ingredient name	Result
phenol	**Rabbit - Eyes - Mild irritant** Duration of treatment/exposure: 0.5 minutes Amount/concentration applied: 5 mg **Rabbit - Eyes - Severe irritant** Amount/concentration applied: 5 mg

Conclusion/Summary [Product] : Not applicable.

Respiratory corrosion/irritation

Not available.

Section 11. Toxicological information

Conclusion/Summary [Product] : Not applicable.

Respiratory or skin sensitization

Not available.

Skin

Conclusion/Summary [Product] : Not applicable.

Respiratory

Conclusion/Summary [Product] : Not applicable.

Specific target organ toxicity (single exposure)

Not applicable.

Specific target organ toxicity (repeated exposure)

Not applicable.

Aspiration hazard

Not applicable.

Information on the likely routes of exposure

Not available.

Potential acute health effects

Not applicable.

Potential chronic health effects

Not available.

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
ADVOCIN (danofloxacin mesylate) Injectable Solution	411.2	N/A	N/A	N/A	N/A
2-pyrrolidone	328	N/A	N/A	N/A	N/A
phenol	317	630	N/A	0.316	N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result
2-pyrrolidone	**Acute - EC50 - Fresh water** Daphnia - Water flea - *Daphnia pulex* - Neonate Age: <24 hours 13.21 mg/l [48 hours] Effect: Intoxication **Acute - LC50 - Fresh water** STDMETH Fish - Fathead minnow - *Pimephales promelas* >100 mg/l [96 hours] Effect: Mortality
phenol	**Acute - LC50 - Fresh water** Fish - common carp - *Cyprinus carpio* - Larvae Size: 8 mm 1.75 µg/l [96 hours] Effect: Mortality **Chronic - NOEC - Fresh water** Fish - Rainbow trout,donaldson trout - *Oncorhynchus mykiss* 118 µg/l [90 days] Effect: Mortality **Acute - LC50 - Marine water** Crustaceans - Opossum shrimp - *Archaeomysis kokuboi* - Juvenile (Fledgling, Hatchling, Weanling) 800 µg/l [48 hours] Effect: Mortality **Acute - EC50 - Fresh water** Algae - Green algae - *Raphidocelis subcapitata* Age: 4 to 7 days 61.1 µg/l [96 hours] Effect: Population **Chronic - NOEC - Fresh water** Daphnia - Water flea - *Daphnia magna* Age: <24 hours 1.5 mg/l [21 days] Effect: Reproduction **Chronic - NOEC - Marine water** Algae - Neptune's Necklace - *Hormosira banksii* - Gamete 16 µg/l [72 hours] Effect: Development

Persistence and degradability

Not available.

Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
2-pyrrolidone	-0.71	-	Low
phenol	1.47	647	High

Mobility in soil

Soil/Water partition coefficient : Not available.

Section 12. Ecological information

Other adverse effects

No known significant effects or critical hazards.

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not available.	Not available.	Not available.
UN proper shipping name	Not available.	Not available.	Not available.
Transport hazard class(es)	Not available.	Not available.	Not available.
Packing group	-	-	-
Environmental hazards	No.	No.	No.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption**: Not determined

Clean Water Act (CWA) 307: phenol

Clean Water Act (CWA) 311: phenol; Hydrogen chloride; sodium hydroxide

TSCA 12(b) - Chemical export notification

Not applicable.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

Name	%	EHS	SARA 302 TPQ (lbs)	SARA 302 TPQ (gallons)	SARA 304 RQ (lbs)	SARA 304 RQ (gallons)
phenol	<0.1	Yes.	500 / 10000	-	1000	-
Hydrogen chloride	≤0.1	Yes.	500	-	5000	-

SARA 304 RQ : 4000000 lbs / 1816000 kg

SARA 311/312

Classification : ACUTE TOXICITY (oral) - Category 4

Composition/information on ingredients

Name	%	Classification
2-pyrrolidone	≥10 - <25	ACUTE TOXICITY (oral) - Category 4

State regulations

Massachusetts : The following components are listed: 2-PYRROLIDONE; MAGNESIUM OXIDE FUME

New York : None of the components are listed.

New Jersey : The following components are listed: MAGNESIUM OXIDE

Pennsylvania : The following components are listed: 2-PYRROLIDINONE; MAGNESIUM OXIDE

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

Section 15. Regulatory information

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia : Not determined.

Canada : Not determined.

China : Not determined.

Eurasian Economic Union : **Russian Federation inventory**: Not determined.

Japan : **Japan inventory (CSCL)**: Not determined.
Japan inventory (ISHL): Not determined.

New Zealand : Not determined.

Philippines : Not determined.

Republic of Korea : Not determined.

Taiwan : Not determined.

Thailand : Not determined.

Turkey : Not determined.

United States : Not determined.

Viet Nam : Not determined.

Section 16. Other information

Procedure used to derive the classification

Classification	Justification
ACUTE TOXICITY (oral) - Category 4 AQUATIC HAZARD (ACUTE) - Category 2	Calculation method Calculation method

History

Date of issue/Date of revision : 5/30/2025

Date of previous issue : 5/30/2025

Version : 1

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
DOT = Department of Transportation
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
IMO = International Maritime Organization
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available
SGG = Segregation Group
TDG = Transportation of Dangerous Goods
UN = United Nations

References : Not available.

Notice to reader

Section 16. Other information

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.