

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: VESicare LS (solifenacin succinate) Oral Suspension 5 mg/5mL (1 mg/mL)

Chemical Name: Butanedioic acid, compounded with (1S)-(3R)-1-azabicyclo[2.2.2]oct-3-yl 3,4-dihydro-1-phenyl-2(1H)-isoquinolinecarboxylate (1:1)

Formula: C₂₃H₂₆N₂O₂ • C₄H₆O₄

Synonyms: Solifenacin Succinate (YM905) Oral Suspension Formulation

1.2. Intended Use of the Product

Use of the substance/mixture: A muscarinic antagonist indicated for the treatment of neurogenic detrusor overactivity in pediatric patients aged 2 years and older. For professional use only.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Astellas US LLC

1 Astellas Way

Northbrook, IL 60062

Tel.: 800-888-7704

www.us.astellas.com

1.4. Emergency Telephone Number

Emergency Number : 800-727-7003

Medical Communications

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS US classification

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

Solifenacin is a competitive muscarinic receptor antagonist. Muscarinic receptors play an important role in several major cholinergically mediated functions, including contractions of urinary bladder smooth muscle and stimulation of salivary secretion. Medical treatment in cases of overexposure should be treated as an overdose of anti-cholinergic agent. Treat according to locally accepted protocols. EXERCISE CARE TO PREVENT CONTACT OR EXPOSURE. Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Name	Synonyms	Product Identifier	%	GHS US classification
Water	AQUA	(CAS-No.) 7732-18-5	> 60	Not classified
Xylitol	Xylite / Xylite (sugar) / Xyliton / XYLITOL / D-Xylitol	(CAS-No.) 87-99-0	< 20	Comb. Dust
1,2-Propanediol	1,2-Propylene glycol / 1,2-Dihydroxypropane / Propane-1,2-diol / Propylene glycol / PROPYLENE GLYCOL	(CAS-No.) 57-55-6	< 5	Not classified
Solifenacin succinate		(CAS-No.) 242478-38-2	< 1	Eye Irrit. 2A, H319

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Benzoic acid, 4-hydroxy-, methyl ester	Methyl p-hydroxybenzoate / Benzoate, 4-hydroxy-, methyl / Methyl 4-hydroxybenzoate / Methyl ester of p-hydroxybenzoic acid / Methylparaben / Benzoic acid, p-hydroxy-, methyl ester / 4-Hydroxybenzoic acid, methyl ester / METHYLPARABEN / Methyl para-hydroxybenzoate / Methyl paraben	(CAS-No.) 99-76-3	< 1	Aquatic Acute 3, H402 Aquatic Chronic 3, H412 Comb. Dust
Propyl 4-hydroxybenzoate	Benzoic acid, 4-hydroxy-, propyl ester / Benzoic acid, p-hydroxy-, propyl ester / n-Propyl p-hydroxybenzoate / Propyl p-hydroxybenzoate / Propylparaben / 4-Hydroxybenzoic acid, propyl ester / PROPYLPARABEN / Propyl para-hydroxybenzoate / n-Propylparaben	(CAS-No.) 94-13-3	< 1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Acute 2, H401 Aquatic Chronic 2, H411 Comb. Dust
2-Propenoic acid, homopolymer	Acrylic resin / Acrylic acid homopolymer / Acrylic acid polymer / Acrylic polymer / Polyacrylic acid / Acrylic acid, polymerized / POLYACRYLIC ACID / Polyacrylate / Propenoic acid, 2-, homopolymer / CARBOMER / Carbomer 934 / Acrylpolymer / Carbomer	(CAS-No.) 9003-01-4	< 1	Comb. Dust
1,2,3-Oxathiazin-4(3H)-one, 6-methyl-, 2,2-dioxide, potassium salt	Acesulfame potassium / 6-Methyl-1,2,3-oxathiazin-4(3H)-one 2,2-dioxide, potassium salt / Potassium salt of 6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide / Acesulfame K / Acesulfame-K / Acesulphame potassium / Acesulfame-potassium / Potassium acesulfame / POTASSIUM ACESULFAME / Acesulphame K / 1,2,3-Oxathiazin-4(3H)-one, 6-methyl-, 2,2-dioxide, potassium salt (1:1)	(CAS-No.) 55589-62-3	< 1	Comb. Dust
Polacrillin Potassium		(CAS-No.) 54182-62-6	< 1	Not classified

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Rinse immediately with plenty of water. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Pharmaceutical. When handling in workplace settings, in quantities that are most likely above the therapeutic dose, this product may be harmful if absorbed through the eyes, skin, or respiratory tract.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

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Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Constipation, dry mouth and urinary tract infection.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Alcohol-resistant foam. Water spray.

Unsuitable Extinguishing Media: Do not use carbon dioxide. Dry chemical. Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: WARNING: Packaging is combustible. Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Use only as directed. Avoid all contact with skin, eyes, or clothing. Avoid breathing (vapor, mist, gas).

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do NOT breathe (vapor, mist, gas).

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: Store at 20°C to 25°C (68°F to 77°F) with excursions permitted from 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Store in original bottle to protect from degradation.

7.3. Specific End Use(s)

A muscarinic antagonist indicated for the treatment of neurogenic detrusor overactivity in pediatric patients aged 2 years and older. For professional use only.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: White to off-white aqueous suspension
Odor	: No data available
Odor Threshold	: No data available
pH	: 5.8 - 6.8
Evaporation Rate	: No data available
Melting Point	: 144 - 149 °C (291.2 - 300.2 °F)
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: 610 mg/mL; freely soluble at room temperature in water, glacial acetic acid, dimethyl sulfoxide, and methanol
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available
Molecular Weight Of Active Ingredient	: 480.55

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

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- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

Solifenacin succinate (242478-38-2)	
Additional Information	In rats (250, 500, 1000, 2000 mg/kg for males and 125, 250, 500, 1000 mg/kg for females), males died at 1000 mg/kg or more and females died at 500 mg/kg or more. Mydriasis was observed at 125 mg/kg or more. Decrease in locomotor activity was observed at 250 mg/kg or more. Prone position, lateral position, salivation, chronic convulsion were observed at 1000 mg/kg or more. In dogs (10, 30, 60 mg/kg), vomiting was observed at 10 mg/kg or more. One female died at 60 mg/kg, which animal showed vomiting, retching, twitch, mydriasis, abnormal gait, incontinence of urine and tonic convulsion.
Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
LD50 Oral Rat	2100 mg/kg
Propyl 4-hydroxybenzoate (94-13-3)	
LD50 Oral Rat	> 5000 mg/kg
1,2-Propanediol (57-55-6)	
LD50 Oral Rat	20 g/kg
LD50 Dermal Rabbit	20800 mg/kg
2-Propenoic acid, homopolymer (9003-01-4)	
LD50 Oral Rat	> 1000 mg/kg
LC50 Inhalation Rat	1.71 mg/l/4h
Xylitol (87-99-0)	
LD50 Oral Rat	16500 mg/kg
Skin Corrosion/Irritation: Not classified pH: 5.8 - 6.8	
Solifenacin succinate (242478-38-2)	
Additional Information	Solifenacin succinate had no antigenicity in the delayed type skin reaction assay in guinea pigs.
Serious Eye Damage/Irritation: Not classified pH: 5.8 - 6.8	
Respiratory or Skin Sensitization: Not classified	
Germ Cell Mutagenicity: Not classified	
Solifenacin succinate (242478-38-2)	
Additional Information	Solifenacin succinate was not mutagenic in the <i>in vitro</i> <i>Salmonella typhimurium</i> or <i>Escherichia coli</i> microbial mutagenicity test or chromosomal aberration test in human peripheral blood lymphocytes with or without metabolic activation, or in the <i>in vivo</i> micronucleus test in rats.
Carcinogenicity: Not classified	
Solifenacin succinate (242478-38-2)	
Additional Information	No increase in tumors was found following the administration of solifenacin succinate to male and female mice for 104 weeks at doses up to 200 mg/kg/day (5 and 9 times, respectively, of the exposure at the maximum recommended human dose [MRHD] of 10 mg), and male and female rats for 104 weeks at doses up to 20 and 15 mg/kg/day, respectively (< 1 times the

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	exposure at the MRHD).
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2-Propenoic acid, homopolymer (9003-01-4)	
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IARC group	3
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Reproductive Toxicity: Not classified

Solifenacin succinate (242478-38-2)	
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Additional Information	<p>Solifenacin succinate had no effect on reproductive function, fertility or early embryonic development of the fetus in male and female mice treated with 250 mg/kg/day (13 times exposure at the MRHD) of solifenacin succinate, and in male rats treated with 50 mg/kg/day (<1 times exposure at the MRHD) and female rats treated with 100 mg/kg/day (1.7 times exposure at the MRHD) of solifenacin succinate.</p> <p>Reproduction studies have been performed in mice, rats and rabbits. After oral administration of ¹⁴C-solifenacin succinate to pregnant mice, drug-related material was shown to cross the placental barrier. No embryotoxicity or teratogenicity was observed in mice treated with 30 mg/kg/day (1.2 times exposure at the maximum recommended human dose [MRHD]).</p> <p>Administration of solifenacin succinate to pregnant mice at doses of 100 mg/kg and greater (3.6 times exposure at the MRHD), during the major period of organ development resulted in reduced fetal body weights. Administration of 250 mg/kg (7.9 times exposure at the MRHD) to pregnant mice resulted in an increased incidence of cleft palate. In utero and lactational exposures to maternal doses of solifenacin succinate of 100 mg/kg/day and greater (3.6 times exposure at the MRHD) resulted in reduced peripartum and postnatal survival, reductions in body weight gain, and delayed physical development (eye opening and vaginal patency).</p> <p>An increase in the percentage of male offspring was also observed in litters from offspring exposed to maternal doses of 250 mg/kg/day. No embryotoxic effects were observed in rats at up to 50 mg/kg/day (<1 times exposure at the MRHD) or in rabbits at up to 50 mg/kg/day (1.8 times exposure at the MRHD). There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, solifenacin succinate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.</p>
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Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Constipation, dry mouth and urinary tract infection.

Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
LC50 Fish 1	59.5 mg/l (Exposure time: 96 h - Species: Oryzias latipes)
EC50 Daphnia 1	11.2 mg/l
ErC50 (algae)	91 mg/l
NOEC chronic crustacea	0.2 mg/l (Species: Daphnia magna)
NOEC chronic algae	20 mg/l

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Propyl 4-hydroxybenzoate (94-13-3)	
LC50 Fish 1	4.1 (4.1 - 8.8) mg/l (Exposure time: 96 h - Species: Danio rerio)
EC50 Daphnia 1	7.97 (7.97 - 32.3) mg/l
NOEC chronic algae	2.1 mg/l
1,2-Propanediol (57-55-6)	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
LC 50 Fish 2	41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
2-Propenoic acid, homopolymer (9003-01-4)	
LC50 Fish 1	580 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)
1,2,3-Oxathiazin-4(3H)-one, 6-methyl-, 2,2-dioxide, potassium salt (55589-62-3)	
LC50 Fish 1	1800 - 2500 mg/l (Exposure time: 96 h - Species: Danio rerio [static])

12.2. Persistence and Degradability

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Persistence and Degradability	Not established.
Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
Persistence and Degradability	Readily biodegradable, according to appropriate OECD test.

12.3. Bioaccumulative Potential

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Bioaccumulative Potential	Not established.
Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
Bioconcentration factor (BCF REACH)	6.4
Log Pow	1.98
1,2-Propanediol (57-55-6)	
BCF fish 1	< 1
Log Pow	-0.92

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Propyl 4-hydroxybenzoate (94-13-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
1,2-Propanediol (57-55-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

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2-Propenoic acid, homopolymer (9003-01-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
Xylitol (87-99-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2 US State Regulations

1,2-Propanediol (57-55-6)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision	: 06/30/2020
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H411	Toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Astellas US GHS SDS