

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Myrbetriq™ Granules (mirabegron for oral suspension)

Chemical Name (of active ingredient): 2-(2-Amino-1,3-thiazol-4-yl)-N-[4-(2-[[[(2R)-2-hydroxy-2-phenylethyl]amino]ethyl]phenyl)acetamide

CAS-No. (of active ingredient): 223673-61-8

Formula (of active ingredient): C₂₁H₂₄N₄O₂S

Synonyms: mirabegron, YM178

1.2. Intended Use of the Product

Use of the Substance/Mixture: The treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency. MYRBETRIQ is a beta-3 adrenergic agonist indicated for the treatment of the symptoms of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years to less than 18 years. 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

Skin Irrit. 2 H315

Eye Irrit. 2 H319

Skin Sens. 1 H317

Repr. 2 H361

STOT RE 2 H373

Aquatic Acute 3 H402

Comb. Dust

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



Signal Word (GHS-US) :

Warning

Hazard Statements (GHS-US) :

May form combustible dust concentrations in air.

H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

H361 - Suspected of damaging fertility or the unborn child.

H373 - May cause damage to organs through prolonged or repeated exposure.

H402 - Harmful to aquatic life.

Precautionary Statements (GHS-US) :

P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P260 - Do not breathe vapors, mist, or spray.

P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

P272 - Contaminated work clothing must not be allowed out of the workplace.

P273 - Avoid release to the environment.

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P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P314 - Get medical advice/attention if you feel unwell.
P321 - Specific treatment (see section 4 on this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

Supplemental Information

: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Proper grounding procedures to avoid static electricity should be followed. Prevent dust accumulation (to minimize explosion hazard). Avoid generating dust.

2.3. Other Hazards

Exposure may aggravate 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. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
D-Mannitol	1,2,3,4,5,6-Hexanehexol / Mannitol, D- / Hexanehexol / MANNITOL / Mannite / Mannitol	(CAS-No.) 69-65-8	> 39	Comb. Dust
Benzenesulfonic acid, ethenyl-, homopolymer, sodium salt	Poly(styrenesulfonate) sodium salt / Polystyrosulfonic acid, sodium salt, homopolymer / Sodium polystyrenesulfonate / Sodium polystyrene sulfonate / Sodium polystyrene sulphonate / Resonium A / Polyethenylbenzenesulphonate sodium / Sulfonated polystyrene, sodium salt / SODIUM POLYSTYRENE SULFONATE	(CAS-No.) 9080-79-9	< 30	Acute Tox. 4 (Inhalation:vapour), H332
Mirabegron	mirabegron	(CAS-No.) 223673-61-8	10	Acute Tox. 4 (Oral), H302 Eye Irrit. 2B, H320 Skin Sens. 1A, H317 Repr. 2, H361 STOT RE 2, H373
Xanthan gum	Gum, xanthan / XANTHAN GUM / Xanthan	(CAS-No.) 11138-66-2	< 5	Comb. Dust

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Cellulose hydroxypropyl methyl ether	Cellulose, 2-hydroxypropyl methyl ether / Hydroxypropyl methylcellulose / Hydroxypropyl methyl cellulose, ether / Hydroxypropyl methyl cellulose / Hydroxypropyl methyl cellulose / Hypromellose / Methylhydroxypropylcellulose / Hydroxypropylmethylcellulose / HYDROXYPROPYL METHYLCELLULOSE / Hydroxypropyl Methylcellulose / Hydroxylpropyl methylcellulose / Hydroxypropylmethyl cellulose / Hydroxymethyl propyl cellulose / 2-Hydroxypropyl cellulose methyl ether / Methocel E50 premium / 2-Hydroxypropylmethyl cellulose / Hypromellose 2910	(CAS-No.) 9004-65-3	< 5	Comb. Dust
Magnesium stearate	Octadecanoic acid, magnesium salt / Stearate, magnesium / Stearic acid, magnesium salt / Octadecanoic acid, magnesium salt (2:1) / Magnesium distearate / MAGNESIUM STEARATE / Salts of stearic acids with magnesium bases / Magnesium octadecanoate / Bis(octadecanoic acid)magnesium salt / Salt of stearic acid with magnesium base / Dioctadecanoate magnesium / magnesium stearate	(CAS-No.) 557-04-0	< 2	Comb. Dust
Hydrochloric acid	Hydrogen chloride / Muriatic acid / HYDROCHLORIC ACID / Hydrochloric acid, anhydrous / hydrochloric acid	(CAS-No.) 7647-01-0	< 2	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
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 / 1,2,3-Oxathiazin-4(3H)-one, 6-methyl-, 2,2-dioxide, potassium salt (1:1) / Acesulphame K / Potassium 6-methyl-4-oxo-4H-1,2,3-oxathiazin-3-ide 2,2-dioxide / acesulfame potassium	(CAS-No.) 55589-62-3	< 2	Comb. Dust
Benzoic acid, 4-hydroxy-, methyl ester	Methyl p-hydroxybenzoate / Benzoate, 4-hydroxy-, methyl / Benzoic acid, p-hydroxy-, methyl ester / Methyl 4-hydroxybenzoate / Methyl ester of p-hydroxybenzoic acid / Methylparaben / METHYLPARABEN / 4-Hydroxybenzoic acid, methyl ester / Methyl parahydroxybenzoate / Methyl paraben / p-Hydroxybenzoic acid, methyl ester	(CAS-No.) 99-76-3	< 2	Aquatic Acute 3, H402 Aquatic Chronic 3, H412 Comb. Dust

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Silica, amorphous	Amorphous silica / Silica / Silica, amorphous, fumed / Silica, colloidal / Silicon dioxide / Silicon dioxide, amorphous / SILICA / Silicon(IV) oxide / Un-crystalline silica / Pigment White 27 / Silicon dioxide (amorphous) / Silicon dioxide amorphous / Silicon(IV)oxide / Silica amorphous / Silicon dioxide containing crystalline and amorphous / Fumed silica / SOLUM DIATOMEAE / silicon dioxide	(CAS-No.) 7631-86-9	< 1	Not classified
Silica, amorphous, precipitated and gel	Precipitated silica / Silica gel / Silica gel, precipitated, crystalline free / Silica, amorphous, gel / Silica gel, crystalline free / Silica gel, precipitated, crystalline-free / Precipitated silica and silica gel / Silica gel, crystalline-free / Hydrated silica / Amorphous silicon dioxide / Synthetic amorphous silicon dioxide / Silica gel, precipitated / Dioxosilane / HYDRATED SILICA / Silica gel, crystal-free / Silica, amorphous and synthetic, precipitated and gel	(CAS-No.) 112926-00-8	< 1	Not classified
Benzoic acid, 4-hydroxy-, ethyl ester	Ethyl p-hydroxybenzoate / Benzoate, 4-hydroxy-, ethyl / Benzoic acid, p-hydroxy-, ethyl ester / p-Carboxyphenol / Ethyl 4-hydroxybenzoate / Ethyl paraben / Ethyl parasept / Ethylparaben / 4-Hydroxybenzoic acid, ethyl ester / ETHYLPARABEN	(CAS-No.) 120-47-8	< 1	Aquatic Acute 3, H402 Aquatic Chronic 3, H412 Comb. Dust
Siloxanes and Silicones, di-Me	Silicones and siloxanes, dimethyl / Siloxanes and silicones, dimethyl / Dimethylpolysiloxane / Dimethicone / KF96 or KE 76 BS / Dimethyl silicones and siloxanes / Polydimethylsiloxane / Dimethyl polysiloxane / KF96 / DIMETHICONE / Siloxanes and Silicones, dimethyl / Polydimethylsiloxanes / Dimethyl(siloxanes and silicones) / Silicone oil / Dimethyl siloxane	(CAS-No.) 63148-62-9	< 1	Not classified
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Hexamethyldisilazane, silica reaction product / Hydrolysis products with silica, silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)- / Hexamethyldisilazane, reaction product with silica / Hydrophobic amorphous fumed silica / Hexamethyl disilazane-treated silica / Pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide	(CAS-No.) 68909-20-6	< 1	Comb. Dust

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: Using proper respiratory protection, move the exposed person to fresh air at once. Encourage exposed person to cough, spit out, and blow nose to remove dust. Immediately call a poison center, physician, or emergency medical service.

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First-aid Measures After Skin Contact: Remove contaminated clothing. Immediately drench affected area with water for at least 15 minutes. If exposed or concerned: Get medical advice/attention.

First-aid Measures After Eye Contact: Immediately rinse 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: Suspected of damaging fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure. Skin sensitization. Causes skin irritation. Causes serious eye irritation.

Symptoms/Injuries After Inhalation: Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction. Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure.

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: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: 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: Combustible Dust.

Explosion Hazard: Dust explosion hazard in air.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: 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.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides.

Other Information: Do not allow run-off from fire fighting to enter drains or water courses. Risk of dust explosion.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe dust. Avoid all contact with skin, eyes, or clothing. Avoid generating dust. Remove ignition sources. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.

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 Personnel

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. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Contact competent authorities after a spill. Use explosion proof vacuum during cleanup, with appropriate filter. Do not mix with other materials. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use only non-sparking tools.

6.4. Reference to Other Sections

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

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

Precautions for Safe Handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid creating or spreading dust. Do not get in eyes, on skin, or on clothing. Do NOT breathe (dust, vapor, mist, gas). Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Keep away from heat, sparks, open flames, and hot surfaces. No smoking.

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. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

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. Store locked up/in a secure area.

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

7.3. Specific End Use(s)

The treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency. For professional use only.

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).

Mirabegron (223673-61-8)		
	Internal OEL Value(s)	50 µg/m ³
Magnesium stearate (557-04-0)		
USA ACGIH	ACGIH OEL TWA	10 mg/m ³ (inhalable particulate matter (Stearates)) 3 mg/m ³ (respirable particulate matter (Stearates))
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (Ceiling)	7 mg/m ³
USA NIOSH	NIOSH REL C [ppm]	5 ppm
USA IDLH	IDLH [ppm]	50 ppm
USA OSHA	OSHA PEL (Ceiling)	7 mg/m ³
USA OSHA	OSHA PEL C [ppm]	5 ppm
Silica, amorphous (7631-86-9)		
USA NIOSH	NIOSH REL (TWA)	6 mg/m ³
USA IDLH	IDLH	3000 mg/m ³
USA OSHA	OSHA PEL (TWA) [1]	6 mg/m ³
USA OSHA	OSHA PEL (TWA) [2]	20 mppcf (80mg/m ³ /%SiO ₂)
Silica, amorphous, precipitated and gel (112926-00-8)		
USA OSHA	OSHA PEL (TWA) [2]	20 mppcf , 80/(SiO ₂) mg/m ³ (See 29 CFR 1910.1000 TABLE Z-3)

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. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

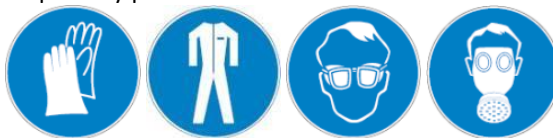
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Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face 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.

Environmental Exposure Controls

: Do not allow the product to be released into the environment.

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	: Solid
Appearance	: Yellowish white colored granules
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
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	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available
Molecular Weight Of Active Ingredient	: 396.51 g/mol

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.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials. Sparks, heat, open flame and other sources of ignition. Dust accumulation (to minimize explosion hazard).
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

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Acute Toxicity (Inhalation): Not classified

Mirabegron (223673-61-8)	
Additional information	In dogs, mirabegron was lethal at a dose of 30 mg/kg, p.o. Acute findings in dogs included increased heart rate and emesis. In rats (800 mg/kg, p.o.), monkeys (60 mg/kg p.o.), and rabbits (30 mg/kg), mirabegron was not lethal. In monkeys and rabbits, acute findings included increased heart rate.

Mirabegron (223673-61-8)	
ATE (Oral)	500.00 mg/kg body weight

Magnesium stearate (557-04-0)	
LD50 Oral Rat	> 2000 mg/kg

Cellulose hydroxypropyl methyl ether (9004-65-3)	
LD50 Oral Rat	≥ 4000 mg/kg

Benzenesulfonic acid, ethenyl-, homopolymer, sodium salt (9080-79-9)	
LD50 Oral Rat	> 8 g/kg
LC50 Inhalation Rat	2600 mg/m ³ (Exposure time: 4 h)
ATE (Vapors)	11.00 mg/l/4h

Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg

1,2,3-Oxathiazin-4(3H)-one, 6-methyl-, 2,2-dioxide, potassium salt (55589-62-3)	
LD50 Dermal Rat	> 2000 mg/kg

Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
LD50 Oral Rat	2100 mg/kg

Benzoic acid, 4-hydroxy-, ethyl ester (120-47-8)	
LD50 Oral Rat	11 g/kg
LD50 Dermal Rabbit	15 g/kg

Silica, amorphous (7631-86-9)	
LD50 Oral Rat	7900 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg (No deaths)

D-Mannitol (69-65-8)	
LD50 Oral Rat	13500 mg/kg

Siloxanes and Silicones, di-Me (63148-62-9)	
LD50 Oral Rat	> 24 g/kg

Skin Corrosion/Irritation: Causes skin irritation.

Serious Eye Damage/Irritation: Causes serious eye irritation.

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Mirabegron (223673-61-8)	
Additional information	Mirabegron showed a moderate skin sensitizing potential in guinea pigs.

Germ Cell Mutagenicity: Not classified

Mirabegron (223673-61-8)	
Additional information	Negative in bacterial reverse mutation assay; negative in chromosomal aberration assay; negative in micronucleus assay.

Carcinogenicity: Not classified

Mirabegron (223673-61-8)	
Additional information	Negative in rat and mouse carcinogenicity test.

Hydrochloric acid (7647-01-0)	
IARC group	3

Silica, amorphous (7631-86-9)	
IARC group	3

Silica, amorphous, precipitated and gel (112926-00-8)	
IARC group	3

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

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Additional information	No effects on fertility or early embryonic development were noted in rats at nonlethal doses (up to 100 mg/kg/day). In rat embryo-fetal development studies, reversible delayed ossification was observed at a dose of 100 mg/kg/day. In rabbits, reduced fetal body weight was observed at a dose of 10 mg/kg/day. At lethal doses in rabbits (30 mg/kg/day), cardiomegaly and dilated aorta were noted.
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Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): May cause damage to organs through prolonged or repeated exposure.

Mirabegron (223673-61-8)	
Additional information	In rats, decreases in circulating platelets and increases in the liver enzyme, alanine transferase were noted. In dogs, repeated doses were associated with increases in respiratory rate, increased heart rate, decreased blood pressure, peripheral vasodilation, and emesis. In monkeys, increases in heart rate and emesis were noted.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction. Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : This material is hazardous to the aquatic environment. Keep out of sewers and waterways. Harmful to aquatic life.

Ecology - Water : Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)
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])
Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
LC50 Fish 1	59.5 mg/l (Exposure time: 96 h - Species: Oryzias latipes)
EC50 - Crustacea [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
Benzoic acid, 4-hydroxy-, ethyl ester (120-47-8)	
LC50 Fish 1	15 mg/l (Exposure time: 96 h - Species: Danio rerio [static])
Silica, amorphous (7631-86-9)	
LC50 Fish 1	5000 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
EC50 - Crustacea [1]	7600 mg/l (Exposure time: 48 h - Species: Ceriodaphnia dubia)
Silica, amorphous, precipitated and gel (112926-00-8)	
LC50 Fish 1	10000 mg/l

12.2. Persistence and Degradability

Myrbetriq™ Granules (mirabegron for oral suspension)	
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

Myrbetriq™ Granules (mirabegron for oral suspension)	
Bioaccumulative Potential	Not established.
Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	
Bioconcentration Factor (BCF REACH)	6.4

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Partition coefficient n-octanol/water (Log Pow)	1.98
Silica, amorphous (7631-86-9)	
BCF Fish 1	(no bioaccumulation expected)

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. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

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

Myrbetriq™ Granules (mirabegron for oral suspension)	
SARA Section 311/312 Hazard Classes	Health hazard - Reproductive toxicity Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Respiratory or skin sensitization Health hazard - Skin corrosion or Irritation Health hazard - Serious eye damage or eye irritation Physical hazard - Combustible dust
Magnesium stearate (557-04-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Cellulose hydroxypropyl methyl ether (9004-65-3)	
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).
Benzenesulfonic acid, ethenyl-, homopolymer, sodium salt (9080-79-9)	
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).
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
Xanthan gum (11138-66-2)	
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).
Benzoic acid, 4-hydroxy-, methyl ester (99-76-3)	

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Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Benzoic acid, 4-hydroxy-, ethyl ester (120-47-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Silica, amorphous (7631-86-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
D-Mannitol (69-65-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Siloxanes and Silicones, di-Me (63148-62-9)	
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).
Silanimine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (68909-20-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Hydrochloric acid (7647-01-0)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
Silica, amorphous (7631-86-9)
U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List
Silica, amorphous, precipitated and gel (112926-00-8)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List

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

Date of Preparation or Latest Revision	: 03/31/2021
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:

Acute Tox. 4 (Inhalation:vapour)	Acute toxicity (inhalation:vapor) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
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 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Eye Irrit. 2B	Serious eye damage/eye irritation Category 2B
Met. Corr. 1	Corrosive to metals Category 1
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization, Category 1
Skin Sens. 1A	Skin sensitization, category 1A
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H290	May be corrosive to metals

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H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H320	Causes eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure
H401	Toxic to aquatic life
H402	Harmful to aquatic life
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.

SDS US (GHS HazCom)