

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version 1.0 Revision Date: 10/07/2019 SDS Number: 4944965-00001 Date of last issue: -
Date of first issue: 10/07/2019

SECTION 1. IDENTIFICATION

Product name : Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Combustible dust

Eye irritation : Category 2A
Reproductive toxicity : Category 1A
Specific target organ toxicity : Category 1 (Kidney, Parathyroid gland)
- repeated exposure

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H319 Causes serious eye irritation.
H360D May damage the unborn child.
H372 Causes damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version 1.0	Revision Date: 10/07/2019	SDS Number: 4944965-00001	Date of last issue: - Date of first issue: 10/07/2019
----------------	------------------------------	------------------------------	--

P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 - < 50
Starch	9005-25-8	>= 30 - < 50
Olmesartan	144689-63-4	>= 10 - < 20
Hydrochlorothiazide	58-93-5	>= 5 - < 10
Amlodipine Besylate	652969-01-2	>= 1 - < 5

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/07/2019	4944965-00001	Date of first issue: 10/07/2019

If swallowed	:	If easy to do, remove contact lens, if worn. Get medical attention.
Most important symptoms and effects, both acute and delayed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Protection of first-aiders	:	Causes serious eye irritation. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin.
Notes to physician	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NO _x) Chlorine compounds Sulfur oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/07/2019	4944965-00001	Date of first issue: 10/07/2019

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
 Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
 Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
 Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
 Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
 Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
 Do not breathe dust.
 Do not swallow.
 Do not get in eyes.
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
 Keep container tightly closed.
 Minimize dust generation and accumulation.
 Keep container closed when not in use.
 Keep away from heat and sources of ignition.
 Take precautionary measures against static discharges.
 Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
 Store locked up.
 Keep tightly closed.
 Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
 Strong oxidizing agents
 Organic peroxides
 Explosives
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
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Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version 1.0 Revision Date: 10/07/2019 SDS Number: 4944965-00001 Date of last issue: -
Date of first issue: 10/07/2019

		(Form of exposure)	ters / Permissible concentration	
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
Starch	9005-25-8	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
Olmesartan	144689-63-4	TWA	30 µg/m ³ (OEB 3)	Internal
		Wipe limit	300 µg/100 cm ²	Internal
Hydrochlorothiazide	58-93-5	TWA	100 µg/m ³ (OEB 2)	Internal
Amlodipine Besylate	652969-01-2	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	100 µg/100 cm ²	Internal

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/07/2019	4944965-00001	Date of first issue: 10/07/2019

Remarks	:	Consider double gloving.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/07/2019	4944965-00001	Date of first issue: 10/07/2019

Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version 1.0 Revision Date: 10/07/2019 SDS Number: 4944965-00001 Date of last issue: -
Date of first issue: 10/07/2019

Product:

Acute oral toxicity : Acute toxicity estimate: 4,839 mg/kg
Method: Calculation method

Components:**Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Starch:

Acute oral toxicity : LD50 (Mouse): > 5,000 mg/kg

Olmesartan:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
LD50 (Mouse): > 2,000 mg/kg
LD50 (Dog): > 1,500 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Hydrochlorothiazide:

Acute oral toxicity : LD50 (Rat): 10,000 mg/kg
LD50 (Mouse): 10,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 990 mg/kg
Application Route: Intravenous
LD50 (Dog): 250 mg/kg
Application Route: Intravenous

Amlodipine Besylate:

Acute oral toxicity : LD50 (Rat): 393 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Olmesartan:**

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version 1.0 Revision Date: 10/07/2019 SDS Number: 4944965-00001 Date of last issue: -
Date of first issue: 10/07/2019

Remarks : No data available

Hydrochlorothiazide:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:**Olmesartan:**

Species : Rabbit
Result : Moderate eye irritation
Method : Draize Test

Hydrochlorothiazide:

Species : Rabbit
Result : Mild eye irritation

Amlodipine Besylate:

Species : Rabbit
Result : Severe irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Olmesartan:**

Routes of exposure : Skin contact
Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:**Cellulose:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo)

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/07/2019	4944965-00001	Date of first issue: 10/07/2019

cytogenetic assay)
 Species: Mouse
 Application Route: Ingestion
 Result: negative

Olmesartan:

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
 Result: negative
- Test Type: Mutagenicity (in vitro mammalian cytogenetic test)
 Result: negative
- Test Type: Chromosome aberration test in vitro
 Test system: Chinese hamster lung cells
 Result: positive
- Test Type: Mouse Lymphoma
 Result: negative
- Genotoxicity in vivo : Test Type: Micronucleus test
 Species: Mouse
 Cell type: Bone marrow
 Application Route: Oral
 Result: negative
- Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Hydrochlorothiazide:

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
 Result: negative
- Test Type: Chromosomal aberration
 Test system: Chinese hamster ovary cells
 Result: negative
- Test Type: sister chromatid exchange assay
 Test system: Chinese hamster ovary cells
 Result: positive
- Test Type: in vitro test
 Test system: mouse lymphoma cells
 Result: positive
- Genotoxicity in vivo : Test Type: Chromosomal aberration
 Species: Chinese hamster
 Cell type: Bone marrow
 Result: negative
- Test Type: in vivo assay
 Species: Mouse
 Cell type: Bone marrow

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/07/2019	4944965-00001	Date of first issue: 10/07/2019

Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Amlodipine Besylate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Olmesartan:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 6 Months
Result : negative

Hydrochlorothiazide:

Species : Mouse, female
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Mouse, male
Application Route : Oral
Exposure time : 2 Years
Result : equivocal

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
Result : negative

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/07/2019	4944965-00001	Date of first issue: 10/07/2019

Amlodipine Besylate:

Species : Mouse
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

Species : Rat
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

IARC Group 2B: Possibly carcinogenic to humans
 Hydrochlorothiazide 58-93-5

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

May damage the unborn child.

Components:

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Ingestion
 Result: negative

Olmesartan:

Effects on fertility : Test Type: Fertility
 Species: Rat
 Application Route: Oral
 Fertility: NOAEL: 1,000 mg/kg body weight
 Result: No effects on fertility.

Effects on fetal development : Test Type: Development
 Species: Rat
 Application Route: Oral
 Dose: 1000 milligram per kilogram
 Result: No teratogenic effects.

Test Type: Development
 Species: Rabbit
 Application Route: Oral

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version 1.0	Revision Date: 10/07/2019	SDS Number: 4944965-00001	Date of last issue: - Date of first issue: 10/07/2019
----------------	------------------------------	------------------------------	--

Dose: 1 milligram per kilogram
Result: No teratogenic effects.

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: \geq 1.6 mg/kg body weight
Symptoms: Malformations were observed., Reduced body weight
Result: Effects on postnatal development.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

Hydrochlorothiazide:

Effects on fertility : Test Type: Fertility
Species: Rat, male and female
Application Route: oral (feed)
Fertility: NOAEL: 4 mg/kg body weight
Result: Effects on fertility.

Test Type: Fertility
Species: Mouse, male and female
Application Route: oral (feed)
Fertility: NOAEL: 100 mg/kg body weight
Result: Effects on fertility.

Effects on fetal development : Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 3,000 mg/kg body weight
Result: No teratogenic effects.

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Result: No teratogenic effects.

Amlodipine Besylate:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Fertility: NOAEL: 10 mg/kg body weight
Result: No effects on fertility.

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Ingestion
Fertility: NOAEL: 25 mg/kg body weight
Result: No effects on fertility.

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/07/2019	4944965-00001	Date of first issue: 10/07/2019

Effects on fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Ingestion
 Developmental Toxicity: LOAEL: 10 mg/kg body weight
 Result: Effects on fetal development.

Test Type: Embryo-fetal development
 Species: Rabbit
 Application Route: Ingestion
 Developmental Toxicity: NOAEL: 10 mg/kg body weight
 Result: No effects on fetal development.

Test Type: Embryo-fetal development
 Species: Mouse
 Application Route: Ingestion
 Developmental Toxicity: LOAEL: 1.6 mg/kg body weight
 Result: Effects on fetal development.
 Remarks: Maternal toxicity observed.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure.

Components:

Hydrochlorothiazide:

Target Organs : Kidney, Parathyroid gland
 Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cellulose:

Species : Rat
 NOAEL : $\geq 9,000$ mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days

Olmesartan:

Species : Rat
 NOAEL : 2,000 mg/kg
 Application Route : Oral
 Exposure time : 24 Months
 Remarks : No significant adverse effects were reported

Hydrochlorothiazide:

Species : Rat, male and female
 LOAEL : 10 mg/kg

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/07/2019	4944965-00001	Date of first issue: 10/07/2019

Application Route : Oral
 Exposure time : 2 y
 Target Organs : Kidney, Parathyroid gland

Species : Mouse, male and female
 NOAEL : 300 - 550 mg/kg
 Application Route : Oral
 Exposure time : 2 y
 Remarks : No significant adverse effects were reported

Species : Dog
 : 50 - 200 mg/kg
 Application Route : Oral
 Exposure time : 9 Months
 Target Organs : Parathyroid gland

Amlodipine Besylate:

Species : Rat
 NOAEL : 15 mg/kg
 Application Route : Oral
 Exposure time : 90 d
 Remarks : No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Components:

Hydrochlorothiazide:

No aspiration toxicity classification

Experience with human exposure

Components:

Olmesartan:

Eye contact : Symptoms: Eye irritation
 Ingestion : Symptoms: hypotension
 Remarks: May cause harm to the unborn child.
 Based on Human Evidence

Hydrochlorothiazide:

Eye contact : Symptoms: Eye irritation
 Ingestion : Symptoms: Dizziness, Headache, Fatigue, Nausea, Abdominal pain, hypotension, dry mouth, electrolyte imbalance, eye pain

Amlodipine Besylate:

Eye contact : Symptoms: Severe irritation
 Ingestion : Symptoms: Nausea, Abdominal pain, Fatigue, Headache, Edema, Palpitation

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version 1.0 Revision Date: 10/07/2019 SDS Number: 4944965-00001 Date of last issue: -
Date of first issue: 10/07/2019

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Cellulose:**

Toxicity to fish : LC50 (*Oryzias latipes* (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Hydrochlorothiazide:

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): > 500 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 500 mg/l
Exposure time: 48 h

Amlodipine Besylate:

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): 2.7 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 3.2 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : IC50 (*Pseudokirchneriella subcapitata* (green algae)): 5.6 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Persistence and degradability**Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

Hydrochlorothiazide:

Stability in water : Hydrolysis: 46.2 %(96 h)

Bioaccumulative potential**Components:****Amlodipine Besylate:**

Partition coefficient: n-octanol/water : log Pow: 3

Mobility in soil

No data available

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/07/2019	4944965-00001	Date of first issue: 10/07/2019

Other adverse effectsNo data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation**49 CFR**Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust
Serious eye damage or eye irritation
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SAFETY DATA SHEET



Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

Version 1.0 Revision Date: 10/07/2019 SDS Number: 4944965-00001 Date of last issue: -
Date of first issue: 10/07/2019

US State Regulations

Pennsylvania Right To Know

Cellulose	9004-34-6
Starch	9005-25-8
Olmesartan	144689-63-4
Hydrochlorothiazide	58-93-5
Croscarmellose sodium	74811-65-7
Amlodipine Besylate	652969-01-2

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Starch	9005-25-8

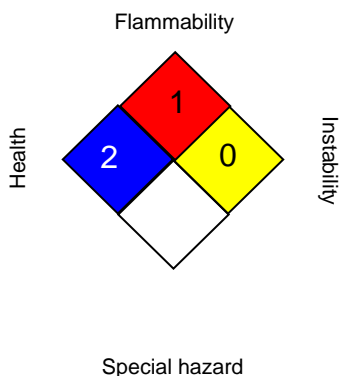
The ingredients of this product are reported in the following inventories:

: not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL : USA. NIOSH Recommended Exposure Limits
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA : 8-hour, time-weighted average
- NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the

Olmesartan / Amlodipine Besylate / Hydrochlorothiazide Formulation

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German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 10/07/2019

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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