



Montelukast Sodium

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 11/12/2015

Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	: Substance
Substance name	: Montelukast Sodium
CAS No.	: 151767-02-1
Product code	: MT
Formula	: C ₃₅ H ₃₅ CINNaO ₃ S
Synonyms	: [R-(E)]-1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]thio]methyl]cyclopropaneacetic acid, monosodium salt
Product group	: Pharmaceutical product

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

1.2.1. Relevant identified uses

Main use category	: Industrial use, Professional use
Industrial/Professional use spec.	: Isolated intermediate
Function or use category	: Antiasthmatic

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Hetero drugs Ltd
7-2-A2, Hetero Corporate, Industrial Estate
500082 Hyderabad - INDIA
T 04023774009
DRRama@heterodrugs.com - www.heterodrugs.com

1.4. Emergency telephone number

No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC or 1999/45/EC

Carc. Cat. 3; R40

Full text of R-phrases: see section 16.

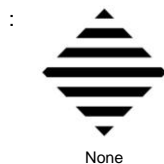
Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



CLP Signal word	: Warning
Hazard statements (CLP)	: H302 - Harmful if swallowed H312 - Harmful in contact with skin
Precautionary statements (CLP)	: P101 - If medical advice is needed, have product container or label at hand P102 - Keep out of reach of children P103 - Read label before use P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood
EUH phrases	: EUH210 - Safety data sheet available on request

2.3. Other hazards

No additional information available

Montelukast Sodium

Safety Data Sheet

according to Regulation (EC) No. 453/2010

SECTION 3: Composition/information on ingredients

3.1. Substances

Name : Montelukast Sodium
CAS No. : 151767-02-1
EC no :
EC index no :

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Ethyl acetate	(CAS No.) 141-78-6 (EC no) 205-500-4 (EC index no) 607-022-00-5		F; R11 Xi; R36 R66 R67
Dimethyl sulfoxide	(CAS No.) 67-68-5		Not classified
Methanol	(CAS No.) 67-56-1 (EC no) 200-659-6 (EC index no) 603-001-00-X		F; R11 T; R23/24/25-39/23/24/25
Toluene	(CAS No.) 108-88-3 (EC no) 203-625-9 (EC index no) 601-021-00-3		F; R11 Repr.Cat.3; R63 Xn; R48/20-65 Xi; R38 R67
Dichloromethane	(CAS No.) 75-09-2 (EC no) 200-838-9 (EC index no) 602-004-00-3		Carc.Cat.3; R40
Heptane; n-heptane	(CAS No.) 142-82-5 (EC no) 205-563-8 (EC index no) 601-008-00-2		F; R11 Xn; R65 Xi; R38 R67 N; R50-53
Acetonitrile	(CAS No.) 75-05-8 (EC no) 200-835-2 (EC index no) 608-001-00-3		F; R11 Xn; R20/21/22 Xi; R36
2-[2-[3(S)-[3-[2-(7-Chloro-2-quinolinyl)-ethenyl]phenyl]-3-hydroxypropyl]phenyl]-2-propanol			Not classified
2-(1((((R)-1-(3-(2-(7-Chloroquinolin-2-yl)ethyl)phenyl)-3-(2-(2-hydroxypropan-2-yl)phenyl)propyl)sulfanyl)methyl)cyclopropyl)acetic acid			Not classified
1-[[[(1R)-1-[3-[(1E)-2-(7-Chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]thio]methyl]cyclopropane acetamide			Not classified
[1-[[[(1R)-1-[3-[(E)-2-(7-Chloroquinolin-2-yl)ethenyl]phenyl]-3-[2-(1-methylethenyl)phenyl]propyl]sulfanyl]methyl]cyclopropyl]acetic acid			Not classified
[1-[[[1-[3-[(E)-2-(7-Chloroquinolin-2-yl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-ethylethyl)phenyl]propyl]sulfinyl]methyl]cyclopropyl]acetic acid			Not classified
1-[[[(1R)-1-[3-[(Z)-2-(7-Chloroquinolinyl-2-yl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]sulfanyl]methyl]cyclopropyl]acetic acid.			Not classified
1-[[[(1R)-1-[3-[(1R)-1-[[[1-(carboxymethyl)cyclopropyl]methyl]sulfanyl]-2-(7-Chloroquinolin-2-yl)ethyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]sulfanyl]methyl]cyclopropyl]acetic acid.			Not classified
1-[[[(1R)-1-[3-[(1S)-1-[[[1-(carboxymethyl)cyclopropyl]methyl]sulfanyl]-2-(7-Chloroquinolin-2-yl)ethyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]sulfanyl]methyl]cyclopropyl]acetic acid.			Not classified
[1-[[[(1R)-3-(2 acetylphenyl)-1-[3-[(E)-2-(7-Chloroquinolin-2-yl)ethenyl]phenyl]propyl]sulfanyl]methyl]cyclopropyl]acetic acid.			Not classified
[1-[[[(1S)-1-[3-[(E)-2-(7-Chloroquinolin-2-yl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methyl)ethyl]phenyl]propyl]sulfanyl]methyl]cyclopropyl]acetic acid.			Not classified
Hexanes	(CAS No.) 149845-06-7		Not classified
Triethylamine	(CAS No.) 121-44-8 (EC no) 204-469-4 (EC index no) 612-004-00-5		F; R11 Xn; R20/21/22 C; R35
N,N-Diisopropylethylamine			Not classified

Montelukast Sodium

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethyl acetate	(CAS No.) 141-78-6 (EC no) 205-500-4 (EC index no) 607-022-00-5		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Dimethyl sulfoxide	(CAS No.) 67-68-5		Not classified
Methanol	(CAS No.) 67-56-1 (EC no) 200-659-6 (EC index no) 603-001-00-X		Flam. Liq. 2, H225 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Oral), H301 STOT SE 1, H370
Toluene	(CAS No.) 108-88-3 (EC no) 203-625-9 (EC index no) 601-021-00-3		Flam. Liq. 2, H225 Asp. Tox. 1, H304 Repr. 2, H361d Skin Irrit. 2, H315 STOT RE 2, H373 STOT SE 3, H336
Dichloromethane	(CAS No.) 75-09-2 (EC no) 200-838-9 (EC index no) 602-004-00-3		Carc. 2, H351
Heptane; n-heptane	(CAS No.) 142-82-5 (EC no) 205-563-8 (EC index no) 601-008-00-2		Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Asp. Tox. 1, H304 Flam. Liq. 2, H225 Skin Irrit. 2, H315 STOT SE 3, H336
Acetonitrile	(CAS No.) 75-05-8 (EC no) 200-835-2 (EC index no) 608-001-00-3		Flam. Liq. 2, H225 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319
2-[2-[3(S)-[3-[2-(7-Chloro-2-quinolinyl)-ethenyl]phenyl]-3-hydroxypropyl]phenyl]-2-propanol			Not classified
2-(1((((R)-1-(3-(2-(7-Chloroquinolin-2-yl)ethyl)phenyl)-3-(2-(2-hydroxypropan-2-yl)phenyl)propyl)sulfanyl)methyl)cyclopropyl)acetic acid			Not classified
1-((((1R)-1-[3-[(1E)-2-(7-Chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]thio)methyl)cyclopropane acetamide			Not classified
[1-((((1R)-1-[3-[(E)-2-(7-Chloroquinolin-2-yl)ethenyl]phenyl]-3-[2-(1-methylethenyl)phenyl]propyl]sulfanyl)methyl)cyclopropyl]acetic acid			Not classified
[1-((((1R)-1-[3-[(E)-2-(7-Chloroquinolin-2-yl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-ethylethyl)phenyl]propyl]sufinyl)methyl)cyclopropyl]acetic acid			Not classified
1-((((1R)-1-[3-[(Z)-2-(7-Chloroquinolinyl-2-yl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]sulfanyl)methyl)cyclopropyl]acetic acid.			Not classified
1-((((1R)-1-[3-[(1R)-1-[[[1-(carboxymethyl)cyclopropyl]methyl]sulfanyl]-2-(7-Chloroquinolin-2-yl)ethyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]sulfanyl)methyl)cyclopropyl]acetic acid.			Not classified
1-((((1R)-1-[3-[(1S)-1-[[[1-(carboxymethyl)cyclopropyl]methyl]sulfanyl]-2-(7-Chloroquinolin-2-yl)ethyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]sulfanyl)methyl)cyclopropyl]acetic acid.			Not classified
[1-((((1R)-3-(2 acetylphenyl)-1-[3-[(E)-2-(7-Chloroquinolin-2-yl)ethenyl]phenyl]propyl]sulfanyl)methyl)cyclopropyl]acetic acid.			Not classified
[1-((((1S)-1-[3-[(E)-2-(7-Chloroquinolin-2-yl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methyl)ethyl]phenyl]propyl]sulfanyl)methyl)cyclopropyl]acetic acid.			Not classified
Hexanes	(CAS No.) 149845-06-7		Not classified
Triethylamine	(CAS No.) 121-44-8 (EC no) 204-469-4 (EC index no) 612-004-00-5		Flam. Liq. 2, H225 Skin Corr. 1A, H314 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Oral), H302
N,N-Diisopropylethylamine			Not classified

Full text of R-, H- and EUH-phrases: see section 16.

3.2. Mixtures

Not applicable

Montelukast Sodium

Safety Data Sheet

according to Regulation (EC) No. 453/2010

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Allow the victim to rest in a well ventilated area. Seek immediate Medical attention. Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid measures after inhalation	: Allow the victim to rest in a well ventilated area. Seek immediate Medical attention. Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention. Remove to fresh air and keep patient at rest. Seek medical attention immediately.
First-aid measures after skin contact	: Immediately wash skin with soap and copious Amounts of waterfor at least 15 minutes. If Irritation persists seek medical attention . Wash immediately with lots of water-Sope may be used-Do not apply(chemical)neutralizing agents-Take victim to a doctor if irritation persists.
First-aid measures after eye contact	: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Rinse immediately with lots of water-Do not apply neutralizing agents-Take victim to an ophthalmoglogist if irritation persists.
First-aid measures after ingestion	: If swallowed, wash out mouth with water, provided Person is conscious. Seek medical advice. Rinse mouth with water-Immediately after ingestion:give lots of water to drink.

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

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use carbon dioxide, dry chemical.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Flammable with air within explosin limits Indirect fire hazard may be ignited by sparks Gas/vapour spreads at floor level:ignition hazard.
Explosion hazard	: Not expected for the product, although the packaging is combustible.
Reactivity	: Reacts slowly with air-Upon combustion CO and CO2 are formed-And formation of metallic fumes-Reacts with (some)-metals.

5.3. Advice for firefighters

Precautionary measures fire : Fight fire from a safe distance. Wear full protective clothing. Use water spray to keep exposed containers and equipment cool. Toxic, corrosive of flammable thermal decomposition products are expected when the product is exposed to fire. Self-contained breathing apparatus and full protective equipment is recommended for firefighters.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Keep upwind-Mark the danger area-Consider evacuation-Seal off low-lying area-Close doors and windows of adjecent premiss.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
Other information	: Wash clothing and equipment after handling.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Gloves.
Handling temperature	: 25 °C

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: "Preserve in tight light -resistant containers, Store at 25°C, excursions permitted between 15°C and 30°C".
Storage temperature	: 25 °C

Montelukast Sodium

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Storage area : Room.
Special rules on packaging : Triple laminated aluminium package.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal protective equipment : Dust production: dust mask with filter type P2. Gloves. Protective clothing. Protective goggles.



Materials for protective clothing : Chloroprene rubber nitrile rubber.

Hand protection : Gloves.

Eye protection : Protective goggles.

Skin and body protection : Protective clothing.

Respiratory protection : Gas mask with filter type A.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : A white or almost white, hygroscopic powder
Molecular mass : 608.18
Colour : White.
Odour : None.
Odour threshold : No data available
pH : No data available
Melting point : No data available
Solidification point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butylacetate=1) : No data available
Flammability (solid, gas) : No data available
Explosive limits : No data available
Vapour pressure : No data available
Relative vapour density at 20 °C : No data available
Relative density : No data available
Solubility : Freely soluble in water and methylene chloride, freely soluble to very soluble in alcohol.
Log Pow : No data available
Log Kow : No data available
Self ignition temperature : No data available
Decomposition temperature : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reacts slowly with air-Upon combustion CO and CO₂ are formed-And formation of metallic fumes-Reacts with (some)-metals.

Montelukast Sodium

Safety Data Sheet

according to Regulation (EC) No. 453/2010

10.2. Chemical stability

Stable under defined conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

As a precautionary measure. Keep away from strong oxidizers.

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Freely soluble in water.
Ecology - air	: Not dangerous for the ozone layer(1999/45/EC).

12.2. Persistence and degradability

Montelukast Sodium (151767-02-1)	
Persistence and degradability	% biodegradation.
Triethylamine (121-44-8)	
Persistence and degradability	% biodegradation.

12.3. Bioaccumulative potential

Montelukast Sodium (151767-02-1)	
Bioaccumulative potential	The substance has low potential for bioaccumulation.
Triethylamine (121-44-8)	
Bioaccumulative potential	The substance has low potential for bioaccumulation.

12.4. Mobility in soil

Montelukast Sodium (151767-02-1)	
Ecology - soil	The substance has moderate mobility in soil.
Triethylamine (121-44-8)	
Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other information : No other effects known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Additional information : Wash clothing and equipment after handling.

Montelukast Sodium

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Ecology - waste materials : Take up liquid spill into absorbent material-Scoop absorbed substance into closing containers.

SECTION 14: Transport information

No dangerous good in sense of transport regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No Annex XVII restrictions

Contains no REACH candidate substance

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Training advice : Normal use of this product shall imply use in accordance with the instructions on the packaging.

Full text of R-, H- and EUH-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Asp. Tox. 1	Aspiration hazard Category 1
Carc. 2	Carcinogenicity Category 2
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Flam. Liq. 2	Flammable liquids Category 2
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1A	skin corrosion/irritation Category 1A
Skin Irrit. 2	skin corrosion/irritation Category 2
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapour
H301	Toxic if swallowed
H302	Harmful if swallowed
H304	May be fatal if swallowed and enters airways
H311	Toxic in contact with skin
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H319	Causes serious eye irritation
H331	Toxic if inhaled
H332	Harmful if inhaled
H336	May cause drowsiness or dizziness
H351	Suspected of causing cancer
H361d	Suspected of damaging the unborn child.
H370	Causes damage to organs
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
R11	Highly flammable.
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed.
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R35	Causes severe burns.
R36	Irritating to eyes.
R38	Irritating to skin.
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R40	Limited evidence of a carcinogenic effect
R48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation.

Montelukast Sodium

Safety Data Sheet

according to Regulation (EC) No. 453/2010

R50	Very toxic to aquatic organisms.
R53	May cause long-term adverse effects in the aquatic environment.
R63	Possible risk of harm to the unborn child.
R65	Harmful: may cause lung damage if swallowed.
R66	Repeated exposure may cause skin dryness or cracking.
R67	Vapours may cause drowsiness and dizziness.
C	Corrosive
F	Highly flammable
N	Dangerous for the environment
T	Toxic
Xi	Irritant
Xn	Harmful

SDS EU (REACH Annex II)

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.