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Revision Number 1

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product Description: **Montelukast sodium**  
 Cat No. : **456440000; 456440010**  
 CAS-No 151767-02-1  
 Molecular Formula C<sub>35</sub> H<sub>35</sub> Cl N O<sub>3</sub> S . Na

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

Recommended Use Laboratory chemicals  
 Uses advised against No Information available

### 1.3. Details of the supplier of the safety data sheet

Company Acros Organics BVBA  
 Janssen Pharmaceuticaaan 3a  
 2440 Geel, Belgium  
 E-mail address begel.sdsdesk@thermofisher.com

### 1.4. Emergency telephone number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11  
 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99  
**CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

#### CLP Classification - Regulation (EC) No 1272/2008

##### Physical hazards

Based on available data, the classification criteria are not met

##### Health hazards

Serious Eye Damage/Eye Irritation

Category 1

##### Environmental hazards

Based on available data, the classification criteria are not met

#### Classification according to EU Directives 67/548/EEC or 1999/45/EC

Symbol(s) Xi - Irritant

R-phrases R41 - Risk of serious damage to eyes

For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16

### 2.2. Label elements

**Signal Word****Danger****Hazard Statements**

H318 - Causes serious eye damage

**Precautionary Statements**

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310 - Immediately call a POISON CENTER or doctor/ physician

**2.3. Other hazards**

No information available

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS****3.1. Substances**

Component	CAS-No	EC-No.	Weight %	CLP Classification - Regulation (EC) No 1272/2008	DSD Classification - 67/548/EEC
Montelukast sodium	151767-02-1		>95	Eye Dam. 1 (H318)	Xi; R41

*For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16***SECTION 4: FIRST AID MEASURES****4.1. Description of first aid measures****General Advice**

If symptoms persist, call a physician.

**Eye Contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.

**Skin Contact**

Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention.

**Ingestion**

Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.

**Inhalation**

Move to fresh air. If breathing is difficult, give oxygen. Obtain medical attention.

**Protection of First-aiders**

Use personal protective equipment.

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

None reasonably foreseeable. Causes eye burns.

**4.3. Indication of any immediate medical attention and special treatment needed****Notes to Physician**

Treat symptomatically.

**SECTION 5: FIREFIGHTING MEASURES**

**SECTION 5: FIREFIGHTING MEASURES****5.1. Extinguishing media****Suitable Extinguishing Media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**Extinguishing media which must not be used for safety reasons**

No information available.

**5.2. Special hazards arising from the substance or mixture**

Thermal decomposition can lead to release of irritating gases and vapors

**Hazardous Combustion Products**

None under normal use conditions

**5.3. Advice for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

**SECTION 6: ACCIDENTAL RELEASE MEASURES****6.1. Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Ensure adequate ventilation. Avoid dust formation.

**6.2. Environmental precautions**

Should not be released into the environment.

**6.3. Methods and material for containment and cleaning up**

Sweep up or vacuum up spillage and collect in suitable container for disposal. Keep in suitable, closed containers for disposal.

**6.4. Reference to other sections**

Refer to protective measures listed in Sections 8 and 13.

**SECTION 7: HANDLING AND STORAGE****7.1. Precautions for safe handling**

Wear personal protective equipment. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

**7.2. Conditions for safe storage, including any incompatibilities**

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from direct sunlight.

**7.3. Specific end use(s)**

Use in laboratories

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1. Control parameters****Exposure limits**

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

**Biological limit values**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

**Monitoring methods**

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

**Derived No Effect Level (DNEL)** No information available.

<u>Route of exposure</u>	<b>Acute effects (local)</b>	<b>Acute effects (systemic)</b>	<b>Chronic effects (local)</b>	<b>Chronic effects (systemic)</b>
Oral				
Dermal				
Inhalation				

**Predicted No Effect Concentration (PNEC)** No information available.

**8.2. Exposure controls****Engineering Measures**

Ensure that eyewash stations and safety showers are close to the workstation location.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source.

**Personal protective equipment**

**Eye Protection** Goggles (European standard - EN 166)

**Hand Protection** Protective gloves

<b>Glove material</b>	<b>Breakthrough time</b>	<b>Glove thickness</b>	<b>EU standard</b>	<b>Glove comments</b>
Natural rubber	See manufacturers	-	EN 374	(minimum requirement)
Nitrile rubber	recommendations			
Neoprene				
PVC				

**Skin and body protection** Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatibility, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

**Respiratory Protection** When workers are facing concentrations above the exposure limit they must use appropriate certified respirators  
To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly.

**Large scale/emergency use** Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced..  
**Recommended Filter type:** Particulates filter conforming to EN 143.

**Small scale/Laboratory use** Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.  
**Recommended half mask:-** Particle filtering: EN149:2001  
When RPE is used a face piece Fit Test should be conducted.

**Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice.

**Environmental exposure controls** No information available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Appearance</b>		
<b>Physical State</b>	Solid.	
<b>Odor</b>	No information available	
<b>Odor Threshold</b>	No data available	
<b>pH</b>	No information available.	
<b>Melting Point/Range</b>	115°C / 239°F	
<b>Softening Point</b>	No data available	
<b>Boiling Point/Range</b>	No information available.	
<b>Flash Point</b>	No information available.	<b>Method -</b> No information available
<b>Evaporation Rate</b>	Not applicable	Solid
<b>Flammability (solid,gas)</b>	No information available	
<b>Explosion Limits</b>	No data available.	
<b>Vapor Pressure</b>	No data available	
<b>Vapor Density</b>	Not applicable	Solid
<b>Specific Gravity / Density</b>	No data available	
<b>Bulk Density</b>	No data available	
<b>Water Solubility</b>	Very soluble	
<b>Solubility in other solvents</b>	No information available	
<b>Partition Coefficient (n-octanol/water)</b>		
<b>Autoignition Temperature</b>	Not applicable	
<b>Decomposition temperature</b>	> 115°C	
<b>Viscosity</b>	Not applicable	Solid
<b>Explosive Properties</b>	No information available	
<b>Oxidizing Properties</b>	No information available	

### 9.2. Other information

<b>Molecular Formula</b>	C35 H35 Cl N O3 S . Na
<b>Molecular Weight</b>	608.17

## SECTION 10: STABILITY AND REACTIVITY

**10.1. Reactivity** None known, based on information available.

**10.2. Chemical stability** Stable under normal conditions. Light sensitive. Hygroscopic.

### 10.3. Possibility of hazardous reactions

**Hazardous Polymerization** Hazardous polymerization does not occur.  
**Hazardous Reactions** None under normal processing.

**10.4. Conditions to avoid** Incompatible products, Excess heat, Avoid dust formation, Exposure to moist air or water, Exposure to light.

**10.5. Incompatible materials**

None known

**10.6. Hazardous decomposition products**

None under normal use conditions

**SECTION 11: TOXICOLOGICAL INFORMATION****11.1. Information on toxicological effects****Product Information****(a) acute toxicity;**

Oral	No data available
Dermal	No data available
Inhalation	No data available

**(b) skin corrosion/irritation;** No data available**(c) serious eye damage/irritation;** Category 1**(d) respiratory or skin sensitization;**

Respiratory	No data available
Skin	No data available

**(e) germ cell mutagenicity;** No data available**(f) carcinogenicity;** No data available

There are no known carcinogenic chemicals in this product

**(g) reproductive toxicity;** No data available**(h) STOT-single exposure;** No data available**(i) STOT-repeated exposure;** No data available**Target Organs** No information available**(j) aspiration hazard;** Not applicable  
Solid**Symptoms / effects,  
both acute and delayed** No information available**SECTION 12: ECOLOGICAL INFORMATION****12.1. Toxicity****Ecotoxicity effects**

Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants

**12.2. Persistence and degradability****Persistence**

Soluble in water, Persistence is unlikely, based on information available.

**12.3. Bioaccumulative potential**

Bioaccumulation is unlikely

**12.4. Mobility in soil**

The product is water soluble, and may spread in water systems. Will likely be mobile in the environment due to its water solubility. Highly mobile in soils.

**12.5. Results of PBT and vPvB assessment**

No data available for assessment

**12.6. Other adverse effects  
Endocrine Disruptor Information  
Persistent Organic Pollutant  
Ozone Depletion Potential**

This product does not contain any known or suspected endocrine disruptors

This product does not contain any known or suspected substance

This product does not contain any known or suspected substance

**SECTION 13: DISPOSAL CONSIDERATIONS****13.1. Waste treatment methods****Waste from Residues / Unused Products**

Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

**Contaminated Packaging**

Dispose of this container to hazardous or special waste collection point..

**European Waste Catalogue (EWC)**

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.

**Other Information**

Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains. Do not dispose of waste into sewer.

**SECTION 14: TRANSPORT INFORMATION****IMDG/IMO**

Not regulated

**14.1. UN number****14.2. UN proper shipping name****14.3. Transport hazard class(es)****14.4. Packing group****ADR**

Not regulated

**14.1. UN number****14.2. UN proper shipping name****14.3. Transport hazard class(es)****14.4. Packing group****IATA**

Not regulated

**14.1. UN number****14.2. UN proper shipping name****14.3. Transport hazard class(es)****14.4. Packing group****14.5. Environmental hazards**

No hazards identified

**14.6. Special precautions for user**

No special precautions required

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable, packaged goods

**SECTION 15: REGULATORY INFORMATION****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****International Inventories**

X = listed

**National Regulations**

Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

Take note of Dir 94/33/EC on the protection of young people at work

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

**15.2. Chemical safety assessment**

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

**SECTION 16: OTHER INFORMATION****Full text of R-phrases referred to under sections 2 and 3**

R41 - Risk of serious damage to eyes

**Full text of H-Statements referred to under sections 2 and 3**

H318 - Causes serious eye damage

**Legend**

**CAS** - Chemical Abstracts Service

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**IECSC** - Chinese Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**WEL** - Workplace Exposure Limit

**ACGIH** - American Conference of Governmental Industrial Hygienists

**DNEL** - Derived No Effect Level

**RPE** - Respiratory Protective Equipment

**LC50** - Lethal Concentration 50%

**NOEC** - No Observed Effect Concentration

**PBT** - Persistent, Bioaccumulative, Toxic

**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road

**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List

**ENCS** - Japanese Existing and New Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**TWA** - Time Weighted Average

**IARC** - International Agency for Research on Cancer

**PNEC** - Predicted No Effect Concentration

**LD50** - Lethal Dose 50%

**EC50** - Effective Concentration 50%

**POW** - Partition coefficient Octanol:Water

**vPvB** - very Persistent, very Bioaccumulative

**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association

**MARPOL** - International Convention for the Prevention of Pollution from Ships

**ATE** - Acute Toxicity Estimate

**VOC** - Volatile Organic Compounds

**Key literature references and sources for data**

Suppliers safety data sheet,

Chemadvisor - LOLI,

Merck index,

RTECS

**Training Advice**

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

**Creation Date** 24-Apr-2014

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**Revision Summary** Not applicable

**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**



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**Disclaimer**

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**End of Safety Data Sheet**