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

1.1 Product identifiers

Product name : Montelukast sodium hydrate

Product Number : SML0101

Brand : Sigma

REACH No. : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Inc.

3050 SPRUCE ST

ST. LOUIS MO  63103

UNITED STATES

Telephone : +1 314 771-5765

Fax : +1 800 325-5052

1.4 Emergency telephone number

Emergency Phone # : 800-424-9300 CHEMTREC (USA) +1-703-527-3887 CHEMTREC (International) 24 Hours/day; 7 Days/week

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards - none

SECTION 3: Composition informação on ingredients

3.1 Substances

Sigma- SML0101

The life science business of Merck operates as MilliporeSigma in the US and Canada
The life science business of Merck operates as MilliporeSigma in the US and Canada.

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**SECTION 4: First aid measures**

4.1 **Description of first aid measures**

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact
Wash off with soap and plenty of water.

In case of eye contact
Flush eyes with water as a precaution.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 **Most important symptoms and effects, both acute and delayed**
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 **Indication of any immediate medical attention and special treatment needed**
No data available

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**SECTION 5: Firefighting measures**

5.1 **Extinguishing media**

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

5.2 **Special hazards arising from the substance or mixture**
Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas, Sodium oxides

5.3 **Advice for firefighters**
Wear self-contained breathing apparatus for firefighting if necessary.

5.4 **Further information**
No data available

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**SECTION 6: Accidental release measures**

6.1 **Personal precautions, protective equipment and emergency procedures**
Avoid dust formation. Avoid breathing vapours, mist or gas.
For personal protection see section 8.

6.2 **Environmental precautions**
Do not let product enter drains.

6.3 **Methods and materials for containment and cleaning up**
Sweep up and shovel. Keep in suitable, closed containers for disposal.
6.4 **Reference to other sections**  
For disposal see section 13.

**SECTION 7: Handling and storage**

**7.1 Precautions for safe handling**  
Provide appropriate exhaust ventilation at places where dust is formed.  
For precautions see section 2.2.

**7.2 Conditions for safe storage, including any incompatibilities**  
Store in cool place. Keep container tightly closed in a dry and well-ventilated place.  
Recommended storage temperature 2 - 8 °C  
Store with desiccant.

**7.3 Specific end use(s)**  
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

**SECTION 8: Exposure controls/personal protection**

**8.1 Control parameters**

**Components with workplace control parameters**

**8.2 Exposure controls**

**Appropriate engineering controls**  
General industrial hygiene practice.

**Personal protective equipment**

**Eye/face protection**  
Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

**Skin protection**  
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

**Body Protection**  
Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory protection**  
Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**Control of environmental exposure**  
Do not let product enter drains.
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance 
   Form: solid

b) Odour 
   No data available

c) Odour Threshold 
   No data available

d) pH 
   No data available

e) Melting point/freezing point 
   No data available

f) Initial boiling point and boiling range 
   No data available

g) Flash point 
   No data available

h) Evaporation rate 
   No data available

i) Flammability (solid, gas) 
   No data available

j) Upper/lower flammability or explosive limits 
   No data available

k) Vapour pressure 
   No data available

l) Vapour density 
   No data available

m) Relative density 
   No data available

n) Water solubility 
   No data available

o) Partition coefficient: n-octanol/water 
   No data available

p) Auto-ignition temperature 
   No data available

q) Decomposition temperature 
   No data available

r) Viscosity 
   No data available

s) Explosive properties 
   No data available

t) Oxidizing properties 
   No data available

9.2 Other safety information 
   No data available

SECTION 10: Stability and reactivity

10.1 Reactivity 
   No data available

10.2 Chemical stability 
   Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions 
   No data available

10.4 Conditions to avoid 
   No data available
10.5 Incompatible materials
Strong oxidizing agents

10.6 Hazardous decomposition products
Other decomposition products - No data available
Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas, Sodium oxides
In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity
No data available

Skin corrosion/irritation
No data available

Serious eye damage/eye irritation
No data available

Respiratory or skin sensitisation
No data available

Germ cell mutagenicity
No data available

Carcinogenicity
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity
No data available

Specific target organ toxicity - single exposure
No data available

Specific target organ toxicity - repeated exposure
No data available

Aspiration hazard
No data available

Additional Information
RTECS: Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

12.1 Toxicity
No data available

12.2 Persistence and degradability
No data available
12.3 **Bioaccumulative potential**  
No data available

12.4 **Mobility in soil**  
No data available

12.5 **Results of PBT and vPvB assessment**  
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 **Other adverse effects**  
No data available

**SECTION 13: Disposal considerations**

13.1 **Waste treatment methods**

**Product**  
Offer surplus and non-recyclable solutions to a licensed disposal company.

**Contaminated packaging**  
Dispose of as unused product.

**SECTION 14: Transport information**

14.1 **UN number**  
ADR/RID: -  
IMDG: -  
IATA: -

14.2 **UN proper shipping name**  
ADR/RID: Not dangerous goods  
IMDG: Not dangerous goods  
IATA: Not dangerous goods

14.3 **Transport hazard class(es)**  
ADR/RID: -  
IMDG: -  
IATA: -

14.4 **Packaging group**  
ADR/RID: -  
IMDG: -  
IATA: -

14.5 **Environmental hazards**  
ADR/RID: no  
IMDG Marine pollutant: no  
IATA: no

14.6 **Special precautions for user**  
No data available

**SECTION 15: Regulatory information**

15.1 **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.  
International Chemical Weapons Convention (CWC) Schedules of Toxic Chemicals and Precursors: Neither banned nor restricted  
Restrictions on the marketing and use of certain dangerous substances and preparations: Neither banned nor restricted  
Regulation (EC) No 649/2012 of the European: Neither banned nor restricted
15.2 Chemical safety assessment
For this product a chemical safety assessment was not carried out.