

Safety Data Sheet

UN-GHS (Rev.3) (2009)

Status: 01.03.2011

Version: 5.0



EUDRAGIT® S 100

Page 1 of 7

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

EUDRAGIT® S 100

acrylic polymer

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

pharmaceutical and cosmetic excipient for oral and dermal use

Recommended restriction(s) for use: no

1.3. Details of the supplier of the safety data sheet

Evonik Industries AG
Plant Roehm Darmstadt
Chemicals Management
Kirschenallee
64293 Darmstadt
Germany
+49 6151 18 01

E-Mail: cmda@evonik.com

Information provided by :
+49 6151 18 40 76

Emergency telephone number
+49 6151 18 43 42

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

This mixture is not classified according to GHS

GHS-Classification As per UN-GHS

Not applicable.

2.2. Label elements As per UN-GHS

Not applicable.

2.3. Other hazards

|| Dust explosions are generally to be expected with dust-forming organic products.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

3.2. Mixtures

Hazardous Ingredients As per UN-GHS

| Component | CAS-No. | Content | Hazard class / Hazard category / Hazard statement |
|-----------------|---------|-----------|---|
| acrylic polymer | | >= 97,0 % | not applicable |

Safety Data Sheet

UN-GHS (Rev.3) (2009)

Status: 01.03.2011

Version: 5.0



EUDRAGIT® S 100

Page 2 of 7

| | | | |
|-------|-----------|-------------|----------------|
| water | 7732-18-5 | 1,0 - 5,0 % | not applicable |
|-------|-----------|-------------|----------------|

4. FIRST AID MEASURES

4.1. Description of first aid measures

| | |
|--------------|---|
| Inhalation | In case of complaints get medical advice. |
| Skin contact | Wash off with water and soap. |
| Eye contact | If mechanical irritation occurs flush eyes thoroughly with a large amount of water, consult a physician if irritation persists. |
| Ingestion | In case of complaints get medical advice. |

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

None known

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

Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

| | |
|---|---|
| Suitable extinguishing media | water spray, foam, dry chemical, carbon dioxide |
| Extinguishing media which must not be used for safety reasons | full water jet |

5.2. Special hazards arising from the substance or mixture

None known

5.3. Advice for firefighters

Wear self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Use personal protective clothing. Use breathing apparatus if exposed to vapours/dust/mist/aerosol. High risk of slipping due to leakage/spillage of product.

6.2. Environmental precautions

Prevent product from getting into drains/surface water/groundwater.

6.3. Methods and material for containment and cleaning up

Take up mechanically. Dispose of in accordance with regulations.

6.4. Reference to other sections

For personal protection see section 8.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

| | |
|---|---|
| Safe handling advice | Avoid the formation and deposition of dust. |
| Advice on protection against fire and explosion | Take precautionary measures against static discharges. Dust can form an explosive mixture with air. In the event of fire, cool the endangered product with water. |

Safety Data Sheet

UN-GHS (Rev.3) (2009)

Status: 01.03.2011

Version: 5.0



EUDRAGIT® S 100

Page 3 of 7

7.2. Conditions for safe storage, including any incompatibilities

| | |
|---|--|
| Requirements for storage areas and containers | Store at controlled room temperature (USP, General Notices). Protect against moisture. Any storage between 8°C and 25°C fulfils this requirement. Store in tightly closed containers. Avoid contamination during sampling. |
|---|--|

7.3. Specific end use(s)

no

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

see section 8.2.

8.2. Exposure controls

For monitoring procedures refer to for instance "Empfohlene Analysenverfahren für Arbeitsplatzmessungen", Schriftenreihe der Bundesanstalt für Arbeitsschutz and "NIOSH Manual of Analytical Methods", National Institute for Occupational Safety and Health

| | |
|------------------------|--|
| Protective measures | Do not inhale dust. |
| Hygiene measures | Follow the usual good standards of occupational hygiene. Clean skin thoroughly after work; apply skin cream. Remove contaminated clothing. Store work clothing separately. |
| Respiratory protection | respiratory protection in case of dust formation |
| Hand protection | protective gloves against mechanical risks according to EN 388 |
| General information | Gloves should be replaced regularly, especially after extended contact with the product. For each work-place a suitable glove type has to be selected. |
| Eye protection | tightly fitting goggles |

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

| | |
|--------------------------|---|
| Form | powder |
| Colour | white |
| Odour | faint characteristic odour |
| Softening Temperature | approx. 200 °C |
| Flash point | > 250 °C (ASTM D 1929-68) |
| Ignition temperature | > 400 °C (ASTM D 1929-68) |
| Lower explosion limit | not available |
| Upper explosion limit | not available |
| Bulk density | 500 kg/m ³ (20 °C) |
| Solubility in water | virtually insoluble |
| Solubility (qualitative) | soluble in aqueous alkalis, soluble in acetone, soluble in lower alcohols |
| pH | not applicable |

9.2. Other information

Dust explosions are generally to be expected with dust-forming organic products.

10. STABILITY AND REACTIVITY

10.1. Reactivity

see section 10.2.

Safety Data Sheet

UN-GHS (Rev.3) (2009)

Status: 01.03.2011

Version: 5.0



EUDRAGIT® S 100

Page 4 of 7

10.2. Chemical Stability

This material is considered stable under specified conditions of storage, shipment and/or use.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

High temperature. Depolymerization begins at 200 °C

10.5. Incompatible materials

None reasonably foreseeable.

10.6. Hazardous decomposition products

In case of thermal decomposition, combustible vapours are formed, which are irritating to eyes and respiratory system, mainly consisting of: methyl methacrylate, methacrylic acid

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

| | | |
|---|--|--------------------------------|
| toxicokinetics, metabolism and distribution | The substance is practically not bioavailable | |
| Acute Oral Toxicity | LD50 rat, Practically non-toxic if swallowed LD50 dog | > 5.000 mg/kg > 5.000 mg/kg |
| Acute Dermal Toxicity | LD50 rat, OECD 402, (analogy) (own study), Low toxicity in contact with skin | > 2.000 mg/kg |
| Caustic burning / irritation of skin | rabbit, OECD 404, (analogy) (own study), | not irritating |
| Serious eye damage/eye irritation | rabbit, OECD 405, (analogy) (own study), | slightly irritating |
| Respiratory/skin sensitization | guinea pig, Bühler-test, (analogy) | non-sensitising |
| Aspiration hazard | not applicable | |
| Germ cell mutagenicity | not mutagenic in <i>in vivo</i> and <i>in vitro</i> tests (analogy) | |
| Carcinogenicity | no specific test data available no evidence for hazardous properties (structure-activity-relationships) (analogy) | |
| Reprotoxicity / teratogenicity | non-teratogenic, not embryotoxic (analogy) | |
| Human health hazard assessment | CMR: no | |
| Specific Target Organ Toxicity - Single exposure | no evidence for hazardous properties | |
| Specific Target Organ Toxicity - Repeated exposure | no evidence for hazardous properties | |
| | dog, oral, 6 w, 0 - 2000 mg/kg (analogy) | NOAEL 2.000 mg/kg |

Safety Data Sheet

UN-GHS (Rev.3) (2009)

Status: 01.03.2011

Version: 5.0



EUDRAGIT® S 100

Page 5 of 7

rat, oral, 6 m

NOAEL
100 mg/kg

General information

The fine particles contained in the product may cause mechanical irritations of the skin, eyes and mucous membranes.
Avoid skin and eye contact and inhalation of product dust/aerosols.

12. ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatoxicity, fish LC50 Poecilia reticulata, OECD 203, 96 h (analogy) > 100 mg/l
(own study)

12.2. Persistence and degradability

Persistence and degradability no evidence for hazardous properties (structure-activity-relationships), (analogy)

Biodegradability not readily degradable (analogy)
(own study)

12.3. Bioaccumulative potential

Bioaccumulation no evidence for hazardous properties
(structure-activity-relationships)
(analogy)

12.4. Mobility in soil

Mobility no evidence for hazardous properties (structure-activity-relationships) (analogy)

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment PBT: no
vPvB: no

12.6. Other adverse effects

General Information Do not allow to enter soil, waterways or waste water.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product Waste is non-hazardous. It should be disposed of in accordance with the regulations after consultation of the competent local authorities and the disposal company in a suitable and licensed facility.

Uncleaned packaging Uncontaminated packaging may be taken for recycling. Contaminated packaging should be emptied optimally and after appropriate professional cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of professionally.

14. TRANSPORT INFORMATION

14.1. UN number

see section 14.2.

14.2. UN proper shipping name

Land transport ADR/GGVSEB

Not a dangerous good within the meaning of transportation regulations.

Land transport RID/GGVSEB

Not a dangerous good within the meaning of transportation regulations.

Inland waterway transport ADN/GGVSEB (Germany)

Safety Data Sheet

UN-GHS (Rev.3) (2009)

Status: 01.03.2011

Version: 5.0



EUDRAGIT® S 100

Page 6 of 7

Not a dangerous good within the meaning of transportation regulations.

Shipment by sea IMDG/GGVSee

Not a dangerous good within the meaning of transportation regulations.

Air transport ICAO/IATA

Not a dangerous good within the meaning of transportation regulations.

14.3. Transport hazard class(es)

see section 14.2.

14.4. Packing group

see section 14.2.

14.5. Environmental hazards

if not mentioned in Point 14.2 then it does not apply

14.6. Special precautions for user

see section 14.2.

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

for transportapproval see regulatory information

15. REGULATORY INFORMATION

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

Classification as per Directive 67/548/EC or Directive 1999/45/EC

Labelling in accordance with
directive 1999/45/EC

not applicable

National legislation

Status of Registration

| | |
|------------|---------------------------------------|
| REACH (EU) | preregistered, registered or exempted |
| TSCA (USA) | For FDA use only. |
| DSL (CDN) | listed or exempted |
| AICS (AUS) | listed or exempted |
| METI (J) | listed or exempted |
| ECL (KOR) | listed or exempted |
| PICCS (RP) | listed or exempted |
| IECSC (CN) | listed or exempted |
| HSNO (NZ) | listed or exempted |

16. OTHER INFORMATION

Other information

none

References

relevant manuals and publications
own examinations
own toxicological and ecotoxicological studies
toxicological and ecotoxicological studies of other manufacturers
SIAR
OECD-SIDS
RTK public files

Safety Data Sheet

UN-GHS (Rev.3) (2009)

Status: 01.03.2011

Version: 5.0



EUDRAGIT® S 100

Page 7 of 7

Places marked by || have been amended from the last version.

This information and all further technical advice is based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.

Date of printing : 06.05.2012