

# 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

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### 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
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## 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 <sup>3</sup> (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)	<b>NOAEL</b> 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

Aquatic toxicity, fish

LC50 *Poecilia reticulata*, OECD 203, 96 h (analogy)  
(own study)

> 100 mg/l

### 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

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# Safety Data Sheet

UN-GHS (Rev.3) (2009)

Status: 01.03.2011

Version: 5.0



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**EUDRAGIT® S 100**

Page 7 of 7

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