

E.C. Safety Data Sheet

Status: 17.09.2002

Version: 6.



EVONIK
INDUSTRIES

Page 1 of 5

EUDRAGIT® L 100-55

1. Identification of the Substance/Preparation and of the Company/Undertaking

EUDRAGIT® L 100-55

Recommended use(s):

pharmaceutical and cosmetic excipient for oral and dermal use

Röhm GmbH & Co. KG, Chemische Fabrik

Pharma Polymere

D-64275 Darmstadt

+49 (0) 6151 - 18 - 01

Information provided by

+49 (0) 6151 / 18-35 53

Emergency Number

+49 (0) 6151 / 18-43 42

2. Composition/Information on Ingredients

Copolymer on the basis of ethyl acrylate and methacrylic acid

Hazardous Ingredients

Component	CAS No.	Hazard symbol(s) / R-phrases	Content
acrylic polymer		Xn 20	60.0 - 100.0 %

3. Hazards Identification

Harmful by inhalation.

4. First Aid Measures

After inhalation

Move subject to fresh air and keep him calm. Obtain medical advice.

After contact with eyes

If mechanical irritation occurs flush eyes thoroughly with a large amount of water, consult a physician if irritation persists.

After contact with skin

Wash off with water and soap. Consult a physician if irritation persists.

After Ingestion

In case of complaints get medical advice.

5. Fire-fighting Measures

Suitable extinguishing media

water spray, foam, dry chemical, carbon dioxide

Unsuitable extinguishing media for safety reasons

full water jet

Special protective equipment for fire fighting

Wear self-contained breathing apparatus.

E.C. Safety Data Sheet

Status: 17.09.2002

Version: 6.



EVONIK
INDUSTRIES

Page 2 of 5

EUDRAGIT® L 100-55

6. Accidental Release Measures

Precautionary measures related to people

Avoid dust formation. Use personal protective clothing. Use breathing apparatus if exposed to vapours/dust/mist/aerosol.

Environmental protective measures

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

Methods of cleaning / adsorption

Take up mechanically. Dispose of in accordance with regulations.

7. Handling and Storage

Handling

Instructions on safe handling

Avoid the formation and deposition of dust. On formation of aerosols work in closed systems or prevent an exposition by means of adequate extraction.

Information on fire and explosion protection

Take precautionary measures against static discharges. In the event of fire, cool the endangered product with water.

Storage

Requirements for storage areas and containers

Storage: dry.

Further information on storage conditions

Do not keep at temperatures above + 30°C.

8. Exposure Controls/Personal Protection

Personal protective equipment

General protective measures

Do not inhale dust.

Hygiene measures

Store work clothing separately. Remove contaminated clothing. Follow the usual good standards of occupational hygiene. Use skin protective preparation as preventive skin protection.

Respiratory protection

Refer to section 7 - 'Instructions on safe handling'. On formation of aerosols: short term: filter appliance, filter P2

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

Appearance

Form :	powder
Colour :	white
Odour :	slightly sour

E.C. Safety Data Sheet

Status: 17.09.2002

Version: 6.



EVONIK
INDUSTRIES

Page 3 of 5

EUDRAGIT® L 100-55

Data relevant to safety

Changes in physical state

Softening Temperature	not determined
Boiling Temperature	not applicable
Flash point	> 250 °C (ASTM D1929-68)
Ignition temperature	> 400 °C (ASTM D1929-68)
Spontaneous ignition	not determined
Lower explosion limit	not determined
Upper explosion limit	not determined
Vapour pressure	not applicable
Density	not determined
Bulk density	500 kg/m ³ at 20 °C
Solubility in water	virtually insoluble
Solubility (qualitative)	soluble in aqueous alkalis, soluble in acetone, soluble in lower alcohols
pH-value	not applicable
Viscosity (dynamic)	not applicable
Further information	Dust explosions are generally to be expected with dust-forming organic products.

10. Stability and Reactivity

Thermal decomposition

No decomposition when used as directed.

Hazardous reactions

No hazardous reactions known.

Hazardous decomposition products

None when used as directed. In case of thermal decomposition combustible, the eyes and respiratory system irritating vapours are formed, consisting mainly of: ethyl acrylate, methacrylic acid

11. Toxicological Information

Acute oral toxicity

LD50 rat > 5,000 mg/kg

LD50 dog > 5,000 mg/kg

Acute inhalational toxicity

LC50 rat, 4 h, Inhalation test with spray aerosol = 5 mg/l

The product has been tested as an aerosol of the original dispersion.

Irritant effect on the skin

slightly irritating

4 h, OECD 404

The test has been performed with the original dispersion.

Irritant effect on the eyes

not irritating

4 h, OECD 405

E.C. Safety Data Sheet

Status: 17.09.2002

Version: 6.



EVONIK
INDUSTRIES

EUDRAGIT® L 100-55

Page 4 of 5

Mutagenicity

not mutagenic in bacteria and mammalian cells in vitro

Further information on toxicology

The fine particles contained in the product may cause mechanical irritations of the skin, eyes and mucous membranes.

12. Ecological Information

Information on elimination (persistence and degradability)

Biodegradability

difficultly biodegradable, OECD 302 B, Zahn-Wellens test (modified), 28 d

In waste water treatment plants it is removed by adsorption and precipitation. source: literature (analogy)

Ecotoxicological effect

Fish toxicity

LC50 poecilia reticulata, OECD 203, 96 h

> 100 mg/l

Further information on ecology

Do not allow to enter soil, waterways or waste water

13. Disposal considerations

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.

Code of waste EWC

18 01 07

wastes from natal care, diagnosis, treatment or prevention of disease in humans - chemicals other than those mentioned in 18 01 06

Always check the given waste codes according to the actual conditions of manufacturing, formulation or use in your facilities.

14. Transport Information

Further information

Not a dangerous good within the meaning of transportation regulations.

15. Regulatory Information

Labelling in accordance with directive 1999/45/EC

requires labelling

Hazardous component(s) for labelling

contains acrylic polymer

Hazard symbol(s)

Xn

Harmful

E.C. Safety Data Sheet

Status: 17.09.2002

Version: 6.



EVONIK
INDUSTRIES

EUDRAGIT® L 100-55

Page 5 of 5

R-phrase(s)

20 Harmful by inhalation.

S-phrase(s)

23 Do not breathe spray.
36 Wear suitable protective clothing.

Status of Registration

EINECS/ELINCS : listed

Occupational restrictions

Note for pregnant woman and nursing mothers (EC Directive 92/85/EEC).
Note for juveniles.

16. Other Information

Miscellaneous information

none

R-phrases of relevance from Section 2

20 Harmful by inhalation.

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

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

The information contained herein relates only to the specific material identified. Röhm GmbH & Co. KG believes that such information is accurate and reliable as of the date of this material safety data sheet, but no representation, guarantee or warranty, expressed or implied, is made as to the accuracy, reliability, or completeness of the information. Röhm GmbH & Co. KG urges persons receiving this information to make their own determination as to the information's suitability and completeness for their particular application.

Date of printing : 25.05.2004