

## **EUDRAGIT® and PLASTOID® - Residual Solvents**

Residual Solvents regulated in the ICH Residual Solvents Guideline as quoted in Ph. Eur. 5.4 and USP/NF <1194> are contained in the following EUDRAGIT® products:

### **EUDRAGIT® E 100**

This product contains small amounts of isopropyl alcohol. The concentration is below 0.5 per cent.

### **EUDRAGIT® RL 100**

This product contains small amounts of methanol. The concentration is 0.5 to 1.5% as stated in the E.C. Safety Data Sheet.

**EUDRAGIT® RL PO**  
**EUDRAGIT® RL 30 D**  
**EUDRAGIT® RS 100**  
**EUDRAGIT® RS PO**  
**EUDRAGIT® RS 30 D**

These products contain small amounts of methanol. The concentration is 0.1 to 1.0% as stated in the E.C. Safety Data Sheets.

**EUDRAGIT® L 30 D-55**  
**EUDRAGIT® NE 30 D**  
**EUDRAGIT® NE 40 D**

Small amounts of ethanol may be detectable in these products after longer storage. The concentration is below 0.5 per cent.

The content of residual solvents in the products may be reduced by evaporation during processing.

The ICH guideline does not address the following organic EUDRAGIT® solutions since here isopropyl alcohol and acetone are deliberately used as solvents:

EUDRAGIT® E 12,5  
EUDRAGIT® RL 12,5  
EUDRAGIT® RS 12,5

These products are solutions of polymers in isopropyl alcohol and acetone as given in the Standards Sheets and in the E.C. Safety Data Sheets.

EUDRAGIT® L 12,5  
EUDRAGIT® S 12,5

These products are solutions of polymers in isopropyl alcohol as given in the Standards Sheet and in the E.C. Safety Data Sheets.

Organic solvents are not used in the manufacture, packing and storage of the following products:

EUDRAGIT® L 100  
EUDRAGIT® S 100  
EUDRAGIT® L 100-55  
PLASTOID® B

Our technical advice on the applications of our products is given without obligation. The buyer is responsible for the use and processing of our products and is also liable for observing any third-party rights. Technical data concerning our products are typical values. Subject to alteration.

® = registered trademark

EUDRAGIT = reg. Trademark of Röhm GmbH & Co. KG, Darmstadt, Germany