

## ORGATER TMFO D

Product: **ORGATER TMFO D**

### EU:

Complies with Regulation (EC) No 1935/2004.

The monomers of the polymer included in ORGATER TMFO D are included in Annex I, Table 1 of Regulation (EC) No 10/2011, including its amendments to date, with following restrictions:

- Terephthalic acid: group restriction No 28: SML(T) of 7.5mg/kg expressed as terephthalic acid.
- 1,4-butanediol: group restriction No 30: SML(T) of 5mg/kg expressed as 1,4-butanediol.

The residual amount of terephthalic acid in the polymer less than 0.03%.  
The residual amount of 1,4-butanediol in the polymer less than 0.3%.

According to our supplier, the demoulding agent is not included in Annex I, Table 1 of Regulation (EC) No 10/2011, including its amendments to date.  
However, the demoulding agent meets the requirements of the monograph for Liquid Paraffin, 7th edition of the European Pharmacopeia.

### USA:

The polymer included in ORGATER TMFO D meets the requirements of of 21 CFR 177.1660 "Poly(tetramethyleneterephthalate)".

The demoulding agent meets the requirements of FDA 21 CFR 172.878, and may be used according to this chapter.