



To the customers of Turbo-Fix

Trasadingen, 1st December 2015

**Subject:** Turbo-Fix relevant information regarding REACH regulation

Regulatory Update – 1<sup>st</sup> December 2015

Dear customers,

Substance name:

2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)

EC number: 239-622-4

CAS number: 15571-58-1

has been identified as substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category 1B. The substance has been included in December 2014 to the Candidate List of Substances of Very High Concern (SVHC).

According to the communication obligations by REACH, we have been informed by our supplier that DOTE is present in a concentration above 0.1% (weight by weight) in the filters listed below. DOTE is used as a thermal stabilizer additive in the PVC housing of these filters and health concerns are associated with handling of this chemical in its pure form. However, DOTE is not expected to be released to the environment in measurable quantities in standard use of these filters. The PVC material continues to be listed as biocompatible (USP class IV).

This information therefore concerns following products:

Turbo-Fix- filter 0.45 µm sterile order no. 94752

Turbo-Fix- filter 0.2 µm sterile order no. 94753

The filter 0.45 µm sterile is delivered with the Turbo-Fix-set.

For more information, please visit the European Chemicals Agency (ECHA)  
www: (<http://echa.europa.eu/regulations/reach>).

Thank you

TPP Techno Plastic Products AG