
Implementation of REACH - DOTE

Dear Sir or Madam,

For the implementation of REACH, we provide the following information:

DOTE has been listed in the SVHC list of the European Chemicals Agency ECHA since 17th December 2014 and must therefore be declared in accordance with the REACH regulation if its content is above 0.1% by weight. We comply with this in our official REACH statement.

The inclusion of DOTE in the SVHC list was justified by the classification "reprotoxic 1B". This is the second lowest reprotoxic classification and is based solely on animal studies, not on human findings.

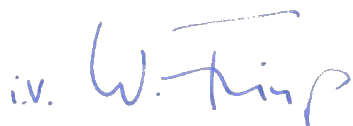
However, recent studies from 2018 have clearly shown that DOTE is not reprotoxic 1B and consequently has to be reclassified to "reprotoxic 2" (lowest classification). However, this reclassification was rejected by the RAC (Risk Assessment Committee) of ECHA in December 2018, despite the clear technical situation. This was done apparently to prevent a precedent (to the return of a substance from the SVHC list) by all means. It is therefore a purely political decision that ignores the technical facts.

On the other hand, DOTE is authorized as an additive in plastics for contact with food, as it is listed in Annex I to Regulation (EU) No 10/2011 (plastic materials and articles intended to come into contact with food). Therefore, DOTE has also been in use for many decades in plastic products for food contact as well as in the pharmaceutical sector.

In addition, it should be noted that DOTE is tightly encapsulated in the PVC polymer matrix and thus not immediately bioavailable.

We hope we had been of assistance to you. Please do not hesitate to contact us for further information needed.

Kind regards



Dr. Wolfgang Frings
Head of Research and Development



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