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Harmonised classification and labelling public consultation

Name: dibutylbis(pentane-2,4-dionato-O,O')tin
EC number: 245-152-0
CAS number: 22673-19-4

The toxicological assessment for reproductive toxicity of the substance dibutylbis(pentane-2,4-dionato-O,O')tin (DBTAcAc) is based on read across data. The evaluating member state justifies their category approach by the definition of a category of different dibutyltin compounds (DBTC, DBTO, DBTM, DBTA, DBTL. We welcome this systematic and databased approach. It is the best we have seen in comparable documents and allows a discussion on scientific grounds

However, our interpretation of the data differs slightly from the CLH proposal.

The majority of the read-across data origin from the DBTC. It has been shown in recent studies, which are correctly cited in the table of studies, that only minor amounts of DBTC are formed. The evaluating Member state points out that under the conditions of the study common in-vitro metabolites are formed out of DBTAcAc and DBTC. The resulting distannoxane species has also been described in literature. The differing interpretation from our side is that DBTAcAc reacts by far faster compared to DBTC, which results in a different bioavailability of the tin compound.

It has been shown in the same type of in-vitro metabolism study, using 119Sn-NMR to identify directly the breakdown products, that DBTL does not form any DBTC at gastric pH value. Besides traces of the already mentioned distannoxane structure the main product of the in-vitro metabolism are complex, probably polymeric structures which could not be further characterized.

Under the same experimental conditions, DBTA hydrolyzes into DBTC

No direct (119-Sn-NMR Method) result exists for DBTM. We do not consider the Schilt study highly significant, since the reaction product DBTC was postulated and the GC Method required derivatisation of the breakdown products and the chemical identity is lost during this step.

In summary, we want to point out the highly differentiated hydrolytical behavior of the tin substance in the defined category which directly impacts the bioavailability (absorption) of the toxophore.

Thus, although there is a clear category definition, we would consider here read across from members of the defined category not as appropriate.

We believe that the respective endpoint should be discussed within a substance evaluation (CoRAP) or a dossier evaluation (Compliance check). This would allow to continue the exemplary scientific discussion initiated by the Swedish MSCA. Such a discussion should as well include the quality of the existing data. This has already been articulated from KEMI side for the studies on DBTC: “These published studies are of variable quality and do not fully comply with regulatory guidelines, but are considered to be sufficiently robust to support the classification proposal as part of a weight of evidence”. Similar argumentation was used by RAC in the past for justification to classify DOTE as Repr. cat. 1B. New studies on the DOTE show no evidence for reproduction toxicity, so the there is to find a notice on the registry of intention to remove Repr. cat. 1B form the DOTE.