

Public substance name: 2,6-di-tert-butylphenol
EC Number (omit if confidential): 204-884-0
CAS Number (omit if confidential): 128-39-2

Hazard endpoint for which vertebrate testing was proposed:

OECD 305 – Bioaccumulation.

Considerations that the general adaptation possibilities of Annex XI of the REACH Regulation were not adequate to generate the necessary information::

available GLP studies – There are no GLP-compliant OECD 305 studies available on the substance.

available non-GLP studies – A single literature paper entitled "Ecotoxicological Profile Analysis VII. Screening Chemicals for their Environmental Behaviour by Comparative Evaluation; Freitag D; Geyer H.; Kraus A.; Viswanathan R.; Kotzias D.; Attar A.; Klein W.; Korte F. (1982)" is available. Within this, the BCF calculated at 3 days cannot be considered reliable as a steady state will not have been reached in this time period. In addition, the difference between the measured concentration of 37 µg/L in the test water and the nominal concentration (50µg/l) indicate that the test substance has been degraded and the fish will therefore have been exposed to the degradation products. The study is not deemed reliable.

historical human data – There are no appropriate historical human data that address the bioaccumulation endpoint on the substance.

(Q)SAR – Using BCFBAF Version 3 contained within Epi Suite Version 4.00 the BCF for 2,6-di-tert-butylphenol was calculated to be 259.5 L/kg wet-wt (Log BCF 2.414). It is considered that this QSAR would be confirmed by the addition of actual data for the bioaccumulation endpoint.

in vitro methods – There are no validated alternative tests that use in vitro methodologies that could be used to meet the standard requirement of the REACH regulation for bioaccumulation.

weight of evidence – Not applicable. The available data on analogues and the substance itself are insufficient to prepare a weight of evidence approach.

grouping and read-across – A published paper on a structural analogue, 2,4-di-tert-butylphenol, CAS 96-76-4, EC 202-532-0, is available, from the Japanese MITI and dated 1992. It was concluded that 2,4 -di-tert-butylphenol has a moderate bioaccumulation potential; however the data is non-GLP and deficient in some areas.

substance-tailored exposure driven testing [if applicable] – Not applicable

[approaches in addition to above [if applicable] – Not applicable

other reasons [if applicable] – Not applicable

- **Considerations that the specific adaptation possibilities of Annexes VI to X (and column 2 thereof) were not applicable** (instruction: free text):

Annex IX, column 2 specific rules for adaptation are given below, together with the reason why they are not adequate for this substance.

9.3.2. The study need not be conducted if:

– the substance has a low potential for bioaccumulation (for instance a log Kow < 3) and/or a low potential to cross biological membranes; or

– direct and indirect exposure of the aquatic compartment is unlikely

The experimentally derived log K_{ow} is 4.50. This result was supported by QSAR calculation which resulted in a log P_{ow} of 4.48. Furthermore the QSAR-tool referred to a further experimental result of 4.92. As direct and indirect exposure of the aquatic compartment cannot be ruled out, further investigation is needed.

Chapter R.11: PBT/vPvB assessment, R.11.4.1.2 Bioaccumulation assessment (B and vB), Figure R.11—4: Integrated assessment and testing strategy for B-assessment. is applied in this case.

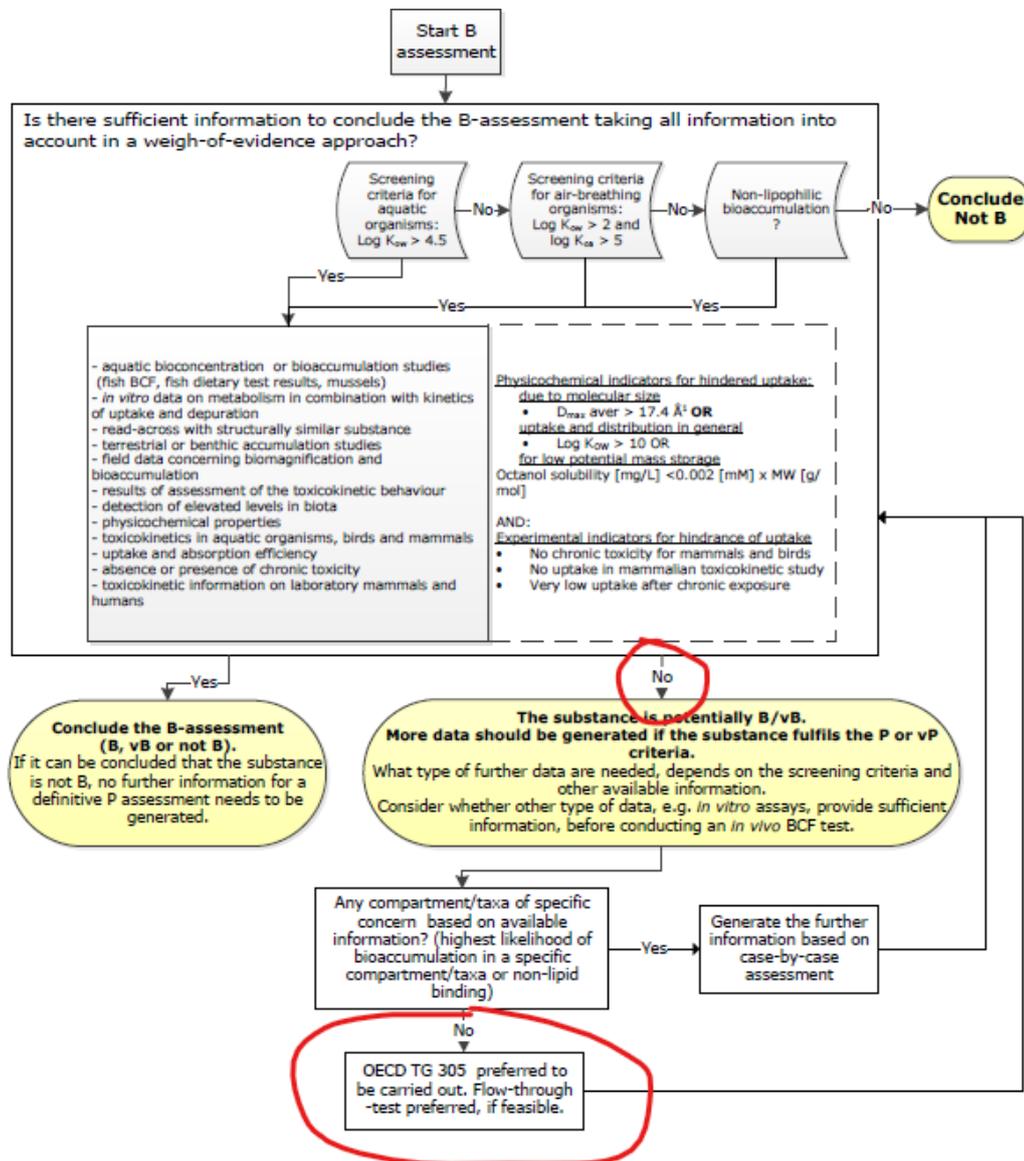


Figure R.11—4: Integrated assessment and testing strategy for B-assessment.

Review of the dossier from the previous decision indicates that further information on bioaccumulation is necessary as the existing data set requires augmentation in order to sufficiently assess the PBT status further. The registrant proposes a further investigation using the OECD 305 study method. The water solubility of 4.11 mg/l indicates that the flow through method rather than a feeding study can be utilised; however sufficient analytical investigation needs to be conducted prior to proceeding with the flow through approach.