AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

TERPHENYL, HYDROGENATED

AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of
Regulation (EC) 1907/2006[1]

Adopted on 1 June 2018

This agreement concerns

Substance name: Terphenyl, hydrogenated

EC number: 262-967-7

CAS number: 61788-32-7

Molecular formula: n.a. (UVCB)

Structural formula: n.a. (UVCB)

[1]Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Finland presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (01 March 2018, submission number SPS-013790-17) on identification of *Terphenyl, hydrogenated* as a substance of very high concern due to its very persistent and very bioaccumulative (vPvB) properties.

The Annex XV dossier was circulated to Member States on 8 March 2018 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 22 May 2018 and agreed in the written procedure of the Member State Committee with closing date of 1 June 2018.

Agreement of the Member State Committee in accordance with Article 59(8):

Terphenyl, hydrogenated is identified as a substance of very high concern because it meets the criteria of Article 57 (e) of Regulation (EC) 1907/2006 (REACH) as a substance which is very persistent and very bioaccumulative in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC) 1907/2006 (REACH).

UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN

A weight-of-evidence determination according to the provisions of Annex XIII of REACH is used to assess the PBT/vPvB properties of the substance. All available information (such as the results of standard tests, modelling and (Q)SAR results) was considered together in a weight-of-evidence approach.

According to the ECHA guidance (ECHA 2017a, R.11), the Weight-of-Evidence determination by expert judgement enables the use of all (screening and assessment) information types listed in Section 3 of Annex XIII to the REACH Regulation in the PBT/vPvB assessment for comparing with the criteria, although not all of these information types can be directly (numerically) compared with the criteria.

Persistence

For the persistence assessment of terphenyl, hydrogenated, most weight is given to half-lives measured in standard simulation tests or simulation tests which are considered comparable to standard tests in terms of reliability and test conditions. Half-lives from such tests can be directly compared with the P/vP criteria. Results from simulation tests with conditions differing from standard tests (or with insufficient documentation), screening tests, QSAR predictions, and microbial culture studies, are used as supporting information.

Based on the weight-of-evidence assessment of available relevant information, terphenyl, hydrogenated fulfils the P and vP criteria. The relevant findings are summarised below:

- Based on available information, abiotic degradation is expected to occur at such a low rate that it is not considered a relevant route of degradation for P/vP assessment
- In a soil simulation test, dissipation half-lives in soil of ≥218 days (temperature-corrected to 12°C) were determined for terphenyl and >224 days quaterphenyl (Monsanto Company 1989) thus fulfilling the P and vP criteria. These half-lives were determined for a mixture of terphenyls, quaterphenyls, and polyphenyls (the proportions of the different isomers are not known). Quaterphenyls and terphenyls are relevant constituents of the UVCB substance.
- In a seawater simulation test with hydrocarbon mixtures (ExxonMobil Biomedical Science, Inc., 2009) primary degradation half-live (temperature-corrected to 12°C) of >182 days was reported for o-terphenyl and half-lives of 32 d and 108 d for m-terphenyl, suggesting that o-terphenyl and m-terphenyl fulfil the P/vP criterion in marine water.
- In an OECD 307 soil simulation test a dissipation half-life of 2-10 days (NOTOX 2009) for p-dicyclohexylbenzene (HT2) was detected during the test when the half-lifes are calculated for the whole test duration using bi-phasic models. Assuming that all non-extractable residues (NER) are parent substance, the half-life is 6-18 days in two soils whereas for one soil no exact half-life can be determined and it is estimated that the half-life for this soil is above test duration, i.e., >120 days. When the second phase (‘slow phase’) from bi-phasic models is used the half-lives were 38-46 days in one soil (with possible underestimation as the kinetic fit was not optimal), 185 days in one soil (with uncertainty as the k_2 parameter was not statistically significant and as the half-life obtained from temperature conversion is longer than the experimental period) whereas for one of the soils, no reliable second-phase half-lives could be determined. In this study a significant part of applied radioactivity partitioned to soil and was quantified as NER, which has a strong influence on the shape of the dissipation curve, which causes uncertainty for the determination of the degradation half-life. The results indicate that p-dicyclohexylbenzene (HT2) is potentially P or vP. Definitive P/vP conclusion has not been drawn in this assessment due to limited data on NER.

- In non-standard biodegradation ultimate biodegradation tests (Monsanto report ES-80-SS34, Monsanto 1977a), degradation of UVCB substances (expected to contain same or structurally similar constituents as terphenyl, hydrogenated) based on CO_2 evolution was at the most 14 % within 35 days, suggesting that the tested substances are not readily biodegradable and therefore potentially P or vP.

- In a river die-away test, when tested separately, o- and p-terphenyl showed no or neglible degradation during 28 days whereas m-terphenyl started to degrade after 16 days. When tested in a mixture of m-, o-, and p-terphenyls, o- terphenyl and m-terphenyl started to biodegrade after 30 days. A HT3 constituent showed no degradation in 30 days whereas HT1 and HT2 constituents were more degradable (Mic 1983a). The results suggest that the tested o-T, p-T, and HT3 constituents are potentially P or vP whereas for the constituents with higher degradation, m-T, HT1, and HT2, no conclusion can be drawn as only primary degradation was measured and, in the case of m-T, as the results were different when tested in mixture or as individual compound.

- A shake-flask carbon dioxide evolution test with a hydrocarbon-adapted inoculum (Mic 1983b) showed relatively low (9-38%) mineralization for o-T, m-T, p-T, p-HT2, p-HT3, and p-Q) in 55 days, suggesting that o-T, m-T, p-T, p-HT2, p-HT3, and p-Q are potentially P or vP. No conclusion can be drawn from this study for p-HT1 as its higher degradation (63%) may be explained by the adapted inoculum.

- In a semi-continuous activated sludge (SCAS) study (Monsanto 1973) the mean disappearance of hydrogenated quaterphenyls (HQ) was 16% at the end of the SCAS study (with negligible volatilization), in a test system considered to be favourable for microbial adaptation. The presence of a detectable amoung of HQ at the end of the following die-away procedure is in line with the results of the SCAS study. The test substance (HQ40) was a mixture of approximately 80 % quaterphenyls with a degree of 40 % hydrogenation (the residual 20 % consists of terphenyl and higher (> 5-ring) phenyl structures). The results suggest that HQ is potentially P or vP.

- P-terphenyl persisted in an SCAS test system (Monsanto 1974) despite the possible adaptation during the test and in a die-away procedure conducted with an inoculum from the SCAS system. Test substance was a mixture containing mainly o-, m-, and p-terphenyls. The results suggest that p-terphenyl is potentially P or vP whereas for m- and o-terphenyl no conclusions can be done due to different concentrations of the isomers in the test substance and possible abiotic losses.

- In a shake-flask carbon dioxide evolution test (Monsanto 1991) with an inoculum pre-exposed to p-terphenyl, p-terphenyl showed no significant mineralisation or primary degradation in 42 days. The CO_2 production after 42 days was 8-9% in the active test and 7% in sterile control. The mean residue recovery after 42 days was 78.0-81.1% of initial level in the active test and 82.1 in sterile control. The results suggest that p-terphenyl is potentially P or vP.

- In a microbial culture study (Ohmori et al 1971) the amounts and properties of microbial strains isolated from environmental samples using terphenyl or other hydrocarbons as a sole carbon source suggest that terphenyl is a less favourable growth substrate compared to other hydrocarbons tested (*n*-paraffin, biphenyl, diphenylmethane, diphenylethane, *trans*-stilbene) and therefore the ultimate degradability of terphenyl in the environment may be limited. The results indicate presence of terphenyl utilizing microorganisms but also suggest that microorganisms able to utilise other hydrocarbons are not necessarily able to utilise terphenyl. The results suggest that o-, m-, and p-terphenyl are potentially P or vP.

- BIOWIN models 3 and 6 in combination indicate that o-T, m-T, p-T, p-HT1, p-HT2, p-Q, p-HQ1, p-HQ2, p-HQ3, and p-HQ4, are potentially P or vP, as the P/vP

screening criteria for this model combination are fulfilled. Regarding HT3 no conclusion can be done as the BIOWIN 3 model is not applicable.

- BIOWIN models 2 and 3 in combination indicate that o-T, m-T, P-T, p-HT1, p-HT2, p-Q, p-HQ1, p-HQ2, p-HQ3, and p-HQ4 do not screen as P or vP. Regarding HT3 no conclusion can be done as the BIOWIN 3 model is not applicable.
- BioHCwin model predicts primary degradation half-lives of 315 days for HT1, 470 days for HT2, 69 days for HT3, 68 days for HQ1, 809 days for HQ2, and 305 days for HQ3, exceeding the P and vP criteria in water (HT1, HT2, HT3, HQ1, HQ2, and HQ3) and in soil and sediment (HT1, HT2, HQ2, HQ3). No conclusion could be done for o-T, m-T, p-T, and Q (for which half-lives were 7-8 days and thus below the P and vP criteria) because BioHCwin model gives a primary biodegradation half-life estimate and because data obtained with mixtures has been used in its training set. Half-lives used to derive the BioHCwin model include results obtained from water, soil, and sediment studies.

Bioaccumulation

For the bioaccumulation assessment of terphenyl, hydrogenated most weight is given to valid measured BCF-values, because these are directly comparable with the criteria. Measured BMF-values and BCF-values derived from these are used as supporting information as well as QSAR predictions.

Based on the weight-of-evidence assessment of available relevant information, terphenyl, hydrogenated fulfils the B and vB criteria because:

- A measured BCF value in Rainbow trout above the vB criterion, 12 993, is determined for o-terphenyl (o-T), a relevant constituent of the UVCB substance (Schlechtriem 2016). This study result is supported by measured BMF values in Rainbow trout, 0.59 (OECD 2012) and 0.2 (ExxonMobil 2010a), which predict BCF-values of 6219 ±1647 and4887 ± 1611, respectively. Based on these data, it is concluded that this constituent is B and vB.
- Measured BCF values for o-terphenyl (o-T) in Carp, 1900 ± 300 and 1100 ± 200, (NITE 2012) are close to the B criterion. (It is noted that these BCF values might be underestimations due to growth dilution.) They are supported by measured BMF values of 0.09 – 0.25, (OECD 2012, Inoue et al. 2012) leading to estimated BCF values of 1575 ± 420 and 1482 ± 549. Based on these data, it is concluded that this constituent is B.
- Partially hydrogenated terphenyls (HT1, HT2) show high measured BCF-values (1551 – 12 436) in Carp and Bluegill (NITE 2004, Monsanto 1983) exceeding the vB criterion. Based on these data, it is concluded that these constituents are B and vB.
- Based on the BCF values measured for m,m-quaterphenyl (Q), 2273 – 3259, (NOTOX 2009b), it can be concluded that this constituent fulfils the B criterion but not the vB criterion. QSAR predictions are 9646 (regression model) and 1499 (Arnot-Gobas), thus supporting this conclusion. Based on these data, it is concluded that this constituent is B.

For some constituents (m-T, p-T, HT3, HQ1, HQ2, HQ3 a definitive conclusion is not possible due to lacking or contradictory data,

- For p-T, HT3, HQ1, HQ2, HQ3 no experimental data on bioaccumulation is available.
- Based on log Kow values (> 4.5), it is concluded that p-T, HT3, HQ1, HQ2 are potentially B and vB.

- For HQ3 the predicted logKow exceeds 10 and the predicted BCF values drop below 500. According to ECHA guidance (ECHA 2014), the aquatic BCF of a substance is probably lower than 2000 if the calculated Log K_{ow} is higher than 10. Therefore, it is concluded that the constituent in probably not B or vB.
- For m-terphenyl QSAR predictions and logKow value indicate that the substance is potentially B. A dietary biomagnification study, on the other hand, shows rapid depuration in rainbow trout ($T_{1/2}$ = 0.52), which corresponds to estimated BCF-values of 636 ± 199. As the information is scarce and contradictory, it is not possible to conclude.

Conclusion: It can be definitively concluded that at least o-terphenyl fulfils both vP and vB criteria. As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1 % w/w), *terphenyl, hydrogenated* is considered to fulfil the vPvB criteria.

Overall conclusion

In conclusion, *terphenyl, hydrogenated* meets the criteria for a vPvB substance according to Article 57 (e) of REACH by comparing all relevant and available information according to Annex XIII of REACH with the criteria set out in the same Annex, in a weight-of-evidence determination.

Reference:

Support Document on *Terphenyl, hydrogenated* (Member State Committee, 1 June 2018)