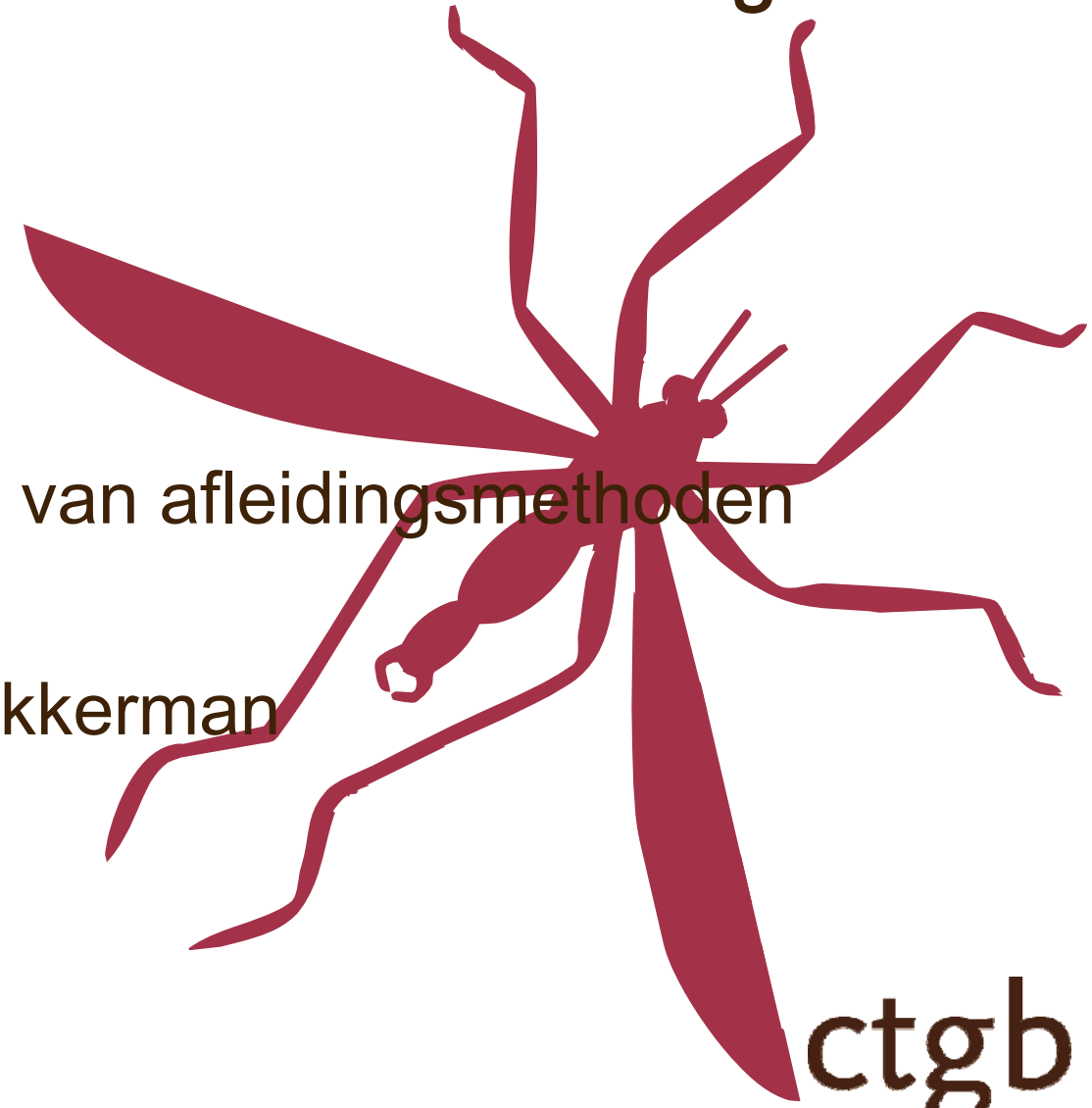
PBT onder Biociden beoordelingen



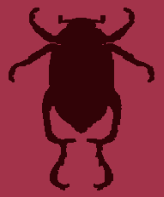
Harmonisatie van afleidingsmethoden

Door Peter Okkerman

16 december 2011

ctgb






Inhoud

- Richtlijn -> verordening
- Dossier vereisten
- Problemen
- Opties ter verbetering

Evt:

- Voorbeelden

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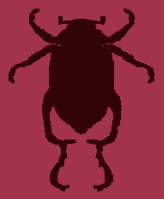

Richtlijn 98/8 (TnsG Annex I inclusion)

POPs, PBT and vPvB substances not be included in Annex I.

unless releases to the environment can be effectively prevented

Reference to the TGD criteria

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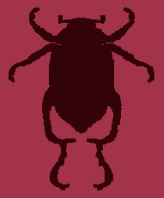


Draft Biocide regulation
Article 5 and 9

1. The following active substances shall not, be included in Annex I:

(e) PBT or vPvB 1907/2006/EC (**REACH**)

(f) 850/2004/EC (**POPs**)

GEEN UNLESS

candidates for substitution

Meets two of the PBT criteria

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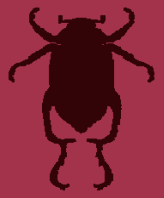


Dossier requirements

Core data:

- Ready/inherent test + photolysis
- Log Kow
- acute D,F,A

Additional:

- Soil degradation
- BCF F
- Koc
- Chronic D, F, A and/or marine
- Soil tox. W,P,B

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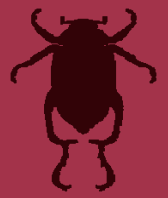


Problemen:

- Overgang TGD -> Reach
- Meestal alleen ready biodeg. test
- Vet gehalte en growth rate correction in vis BCF studie
- Relevantie fotolyse
- Geen chronische ecotox data
- Geen data voor bodem

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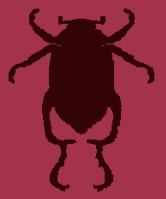


Recommended improvements

- Harmonisation PBT assessment
- Harmonisation endpoint derivation

P: DT50 derivation from test; temperature correction (+ other parameters?); extrapolation to water/sed and soil; QSAR

B: different accumulation mechanisms in different types of organisms requires testing of different species and different B-criteria; e.g. BC(A)F earthworm; (water)plants

T: agreement on extrapolation of acute to chronic endpoint;

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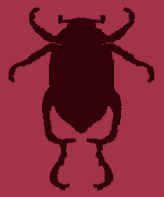


Extra: Voorbeelden

- Tweede generatie anticoagulantia
- Cybutryne (antifouling)
- S-methoprene (insecticide)

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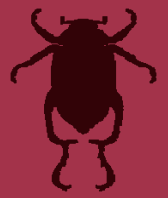


Tweede generatie anticoagulantia

VPersistent

- hydrolytically stable under environmentally relevant conditions (DT_{50} > 1 year).
- not readily biodegradable and does not degrade under anaerobic conditions.
- low biodegradation potential in soil (DT50 = 213 days)
- susceptible to photo-transformation in water (DT_{50} = 1.67d).

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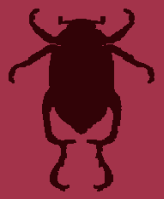


Tweede generatie anticoagulantia

- QSAR BCF values fish range from 4400 (pH = 9) up to 36134 (pH = 7).
- Lowest acute toxicity was observed with a fish species LC50(4d) = 0.07 mg/L. Chronic NOEC is expected below 0.01 mg/L

Conclusion: Potentially vPvBT

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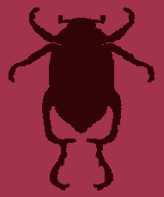


Cybutryne I

P-criterion

not to be ready biodegradable. Cybutryne does not biodegrade in marine sediment, and should therefore be considered as very persistent (vP).

B-criterion

does not bioconcentrate in fish (BCF = 250 L/kg), but the BCF in green macro algae is > 5000 L/kg, indicating that Cybutryne is very bioaccumulative in plants. Cybutryne did not bioaccumulate in other plants. Therewith no biomagnification from plants and macro algae to invertebrates was observed. Cybutryne is therefore not regarded as bioaccumulative.

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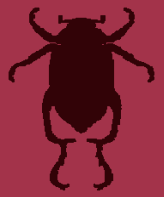


Cybutryne II

T-criterion

The chronic NOEC of Cybutryne for marine and freshwater algae and macrophytes is < 0.01 mg a.s./L and therefore Cybutryne can be classified as toxic for plants. Cybutryne is not considered to be toxic for Carcinogenicity, Mutagenicity and/or Reproduction

Cybutryne fulfils the criteria for Persistence and Toxicity, but not for Bioaccumulation. Therefore, Cybutryne is not classified as a PBT or vPvB substance.

Issues:

- Adsorption/accumulation to plants may result in accumulation in plant eating organisms – relevant for PBT?
- Can micro/mesocosm studies be used for PBT assessment?

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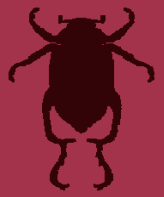


S-methoprene

Persistence

- No DT50 data are available for S-Methoprene in water or sediment. Based on a DT50 value of 22 d (12 °C) in soil which would lead to 220 d for sediment
- not readily biodegradable (between 20.99% and 49.45% degradation after 28 days at concentrations of 2 and 8 mg/l, respectively).
- Hydrolytically, S-Methoprene is stable at environmentally relevant pH levels.
- The active substance is also readily adsorbed to particulates with Koc values ranging between 537 and 1407 l/kg
- Photolytically degradable under aqueous conditions DT50 between 1 and 5 days.

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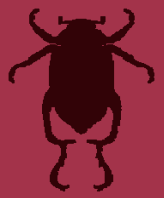


S-methoprene

Bioaccumulation

- log Kow of 9.5 indicates bioaccumulation potential

Toxicity

- 48h EC50 (0.38 mg/l) for Daphnia magna as this was the most sensitive aquatic organism tested

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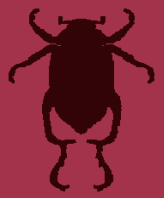


S-methoprene

- Limited data!
- Principle: deg rate sediment 10x lower as deg rate in soil – door geringere zuurstofrijke zone
- Extrapolation of acute LC50 to chronic NOEC?

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