

HAZARD ASSESSMENT OUTCOME DOCUMENT

for

Dimantine

EC No 204-694-8

CAS No 124-28-7

Member State(s): FRANCE

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1. HAZARD SUBJECT TO ASSESSMENT

Dimantine was originally selected for hazard assessment in order to clarify suspected hazard properties:

PBT/vPvB

2. OUTCOME OF HAZARD ASSESSMENT

The available information on the substance and the hazard assessment conducted has led the assessing Authority to the following considerations, as summarised in the table below.

Hazard Assessment Outcome	Tick box
According to the authority's assessment the substance does not have PBT/vPvB properties based on the currently available information.	<input checked="" type="checkbox"/>
According to the authority's assessment the substance has PBT/vPvB properties.	<input type="checkbox"/>
According to the authority's assessment further information would be needed to confirm the PBT/vPvB properties but follow-up work is not relevant or carried out at present.	<input type="checkbox"/>

This outcome is based on the REACH and CLP data as well as other available relevant information.

3. BASIS FOR REASONING

In a weight of evidence approach, it can be considered that dimantine including impurities >0.1% is not persistent. Based on QSAR predictions, dimantine and four of the identified impurities can be considered as not B. This approach is based on speciation and bioaccumulation models and should be validated and supported by other information to definitively state on the B status of dimantine and these impurities. Nevertheless, as dimantine and these impurities are considered as not P, this approach seems reasonable. The B property of the fifth impurity has not been investigated because it has been shown to be not P/vP. The lowest relevant chronic aquatic toxicity value is the ErC10 (72 hours) determined on the freshwater green alga *Desmodesmus subspicatus*: 0.5µg/L. This data is from a read-across with C16 DMA and is similar to experimental data with dimantine (algae NOEC (72h) =5.17 µg/L). Thus according to the criteria from Annex XIII, and with or without read-across, dimantine fulfils the T criterion. Nevertheless, as dimantine including impurities >0.1% has been shown to be not persistent, the substance is not PBT nor vPvB.