

## Public consultation on potential candidates for substitution

### NON-CONFIDENTIAL comments

**Substance** : Polyhexamethylene biguanide Hydrochloride ; **PHMB (1415; 4.7)**  
**Supported PTs** : PT1, PT2, PT4, PT5, PT6  
**EC Number** : Not allocated (polymer)  
**CAS Number** : 32289-58-0 and 1802181-67-4  
**eCA** : France

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**Attached files** :  
**(confidential)** :

- Position Paper (Doc. Pareva ref. 201607-001 (4 July 2016)
- Additional document to Position Paper - Persistance (3 March 2017)
- "PHMB: Simulation Test - Aerobic Sewage Treatment: Activated Sludge Units (Porous Pot Test)" (Study BV58TG, 7 April 2017)
- "PHMB: Algal Growth Inhibition Test" (Study TP54SQ, 7 April 2017)

## COMMENTS

This submission is made in response to the public consultation on PolyHexaMethylene Biguanide hydrochloride (named as PHMB in this document) with a mean number-average molecular weight (Mn) of 1415 and a mean polydispersity Index (PDI) of 4.7, noted PHMB(1415;4.7).

We are submitting the below comments to describe the current situation but also to bring you new information as we believe that PHMB should not be proposed as a candidate for substitution. **Moreover we believe that this new information could be reviewed by the "PBT expert group" to forge an independent opinion about classification of the PHMB.**

PHMB (1415;4.7) is proposed as a "candidate for substitution" as a substance according to the available data in its BPR dossier and according to article 10.1.d of the BPR, as it meets 2 out of the 3 "PBT" criteria of the Annex XIII of REACH. The 2 criteria are Toxicity ("T") and Persistence ("vP").

The first criteria "T" is based on the result of ecotoxicity studies on fish (OECD 210), Daphnia (OECD 211) and Algae (OECD 201) showing that NOECs are < 0.01 mg/L. It is important to understand this "T" criterion is only based on ecotoxicological studies that are performed in clean lab water, not containing any of the compounds that are usually found in natural surface waters (suspended matter, soluble and insoluble organic compounds, sediments,...).

New studies were performed on the most sensitive species (algae and fish at early stage) and showed the toxicity is far lower with the presence of humic acid, a compound found in natural surface waters.

- The NOEC on algae increased from 0.945µg/L to 5.3µg/L in the presence of humic acid.
- The NOEC on fish increased from 4.98µg/L (hatching success, 2013) or 13µg/L (2017) to >67µg/L in the presence of humic acid.

These new studies show that interaction of humic acid (complex soluble organic acids) in water leads to a mitigation of the PHMB toxicity towards non-target organism, such as algae or fish.

It must be emphasised that, in the presence of solid substances (suspended solids and/or sediments) this observation would have been even more noticeable. Indeed, other studies cited lower.

The second criteria "vP" is based on the result of degradation studies performed in soils (guideline OECD 307) or in water/sediment systems (OECD 308).

In both studies, it was observed a very quick combination of PHMB to solid phases of the systems.

In soil, after 1 hour contact time, 89.4% of the applied PHMB was already not extractible.

In water/sediment systems (unstirred system), 89.3% of the applied PHMB was combined to sediments at day 27, its non-extractible part being of 96.2%.

The question of the persistence depends on the potentiality of combined PHMB to be released in the environment when time elapses.

For this issue, ECETOC gives clear definitions that can help answering this question, by classifying the residues:

- Extractable Residues (ER), freely available or only weakly adsorbed to the matrix.
- Not Extractable Residue (NER), needing harsh extraction methods with possibility of alteration of the matrix. But NER are recovered unaffected.
- Bound Residue (BR), often indistinguishable from the natural organic material, that cannot be extracted without being degraded with the matrix

In PHMB case, the apportionment according to these definitions is:

- Extractable Residues (ER) : 5.4 to 8.5%, being considered as a maximum rate because NER part was not measured
- Not Extractable Residue (NER) = not measured
- Bound Residue (BR) : 85.4 to 89.4%

It must be precised that the compound that was recovered after extraction was not precisely identified as PHMB, as the LSC-based methods used only allowed to quantify [<sup>14</sup>C]compounds that were extracted and not specifically PHMB. But, according to the extraction conditions used (strong alkali in high temperature during 16 hours), PHMB was probably decomposed rather than cleanly extracted. So, the affectation of 5.4 to 8.5% of applied PHMB as "Extractible Residue" should be regarded as Bound Residues. However, this figure could be kept for the risk assessment calculation, which would constitute a safety margin.

Regarding the fear to have some bound-PHMB released from a natural matrix, whatever the cause, "freshly released" PHMB will certainly combine again with available natural substrates, as quickly as on the first time.

This also means the Equilibrium Partitioning Method (EPM) that was used for the environmental risk assessment of the PHMB-based biocidal products, is not suitable due to the irreversibility of PHMB strong combination with natural substrates (studies show there are no equilibrium).

Additionally to core data studies, this PHMB behaviour was also demonstrated by an HPLC study (CNRS-ESPCI, 2013). This study consisted in evaluating the global PHMB behaviour towards different solid phases (packed in HPLC columns). This study also showed that PHMB combines very quickly to solids (silica, grafted or not), and is not easily extracted from this phase, even with chemically severe conditions (solvent, pH,...). This study also showed that the presence of organic matter with the solid phase highly strengthen its combination with matrix compounds.

The above information shows that PHMB, due to its well-known properties and its main apportionment in the BR fraction should bring the evaluators to pay attention to the actual potential of PHMB to harm the environment that is certainly lower than calculated because it has low chances to remain free during a sufficient long time. Automatic and uncritical use of raw study results should be avoided in PHMB case.

The physico-chemical observations from above studies were also confirmed by the result of ecotoxicological studies performed on soil and sediment species:

- PHMB : *"Reproduction study (56d) with the earthworm in an artificial soil substrate"* (OECD 222)

Based on measured test concentrations, the most conservative value is the NOEC for body weight : 48.27 mg/kg dw.

- PHMB: *"A prolonged (28d) sediment toxicity test with lumbriculus variegatus using spiked sediment"* (OECD 225)

Based on mean measured test concentrations in the sediment, the most conservative value is the NOEC : 174 mg/kg dwt.

It must be noted that PHMB was administered to the test organism in sediment amended with food, in order to take into account the remarks from evaluators

regarding the toxicity study of PHMB to the Sediment-Dwelling Phase of the Midge *Chironomus riparius* (OECD 218). This route of application didn't lead to worse results.

- PHMB: "A toxicity test (21d) to determine the effects on seedling emergence and growth of terrestrial plants" (OECD 208) on 10 species

Few NOECs were determined under the maximum concentrations tested (until 1000 mg/kg). The NOEC for the most sensitive dicot species, *Cucumis sativus* (cucumber), was 45 mg/kg dry soil, based on seedling height.

These studies show that PHMB effect on soil and sediments are far lower than initially assessed with the data available in the initial dossier. These new data should be taken into account in order to lead to a most realistic risk assessment.

All studies are included in BPR dossiers of Laboratoire Pareva.

Some studies/documents are given with this comment, in confidential part.

The classification of PHMB as a potential "candidates for substitution" is based on "T" and "vP" criteria of the Annex XIII of REACH on PBT substances. As provided for in PBT discussions, the weight of evidence should apply when revising these criteria for these substances. So, the same provision should apply to PHMB.

PHMB could be banned from the list of active biocidal substances because the way in which the results of some important environmental studies are exploited, does not take into account its very specific properties and new studies.

The "PBT expert group" could review this information and settle final classification of the PHMB.

#### To summarise

**PHMB dossier and new information could be reviewed by the PBT expert group to assess whether it has to be classified as a persistent substance. Their opinion would be based on a series of recent studies (available in PHMB dossier) that now constitutes a beam of presumption showing that we believe should not be regarded as such.**