

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 none

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).

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").

We developed in a separate document the reasons why, according to our opinion, PHMB should not be listed as a "candidate for substitution".

But, on a more practical side, we would like to inform about the reasons why our customers (formulators) still like to use PHMB in their applications rather than other actives:

Regarding the cost efficiency

PHMB is often used because of its good efficacy at low concentrations, more particularly on gram positive bacteria, which also makes it interesting in formulations with other biocides to broaden their spectra of efficacy. PHMB is one of the rare biocidal active ingredients that are hydrophilic polymers.

Some applications out of the BPR scope illustrate advantages of PHMB: preservative for contact lenses solutions, preservative in cosmetic products, active in wound dressings to improve wound healing, nose drop & eyes diseases treatment products, preservative of some medicines, etc...

Regarding the handling and storage

PHMB has just to be stored on retention places, which is the case in all premises dedicated to chemicals. It presents no risks of explosion, no risk of aggravation or intensification of a fire. It is even the opposite because it is distributed under a maximum 20%-aqueous solution for industrial uses.

Regarding the use by operators

This 20%-aqueous solution makes PHMB very practical because:

- It can be directly injected in the water flow for the water treatment applications (existing pumps are available with corresponding flow rates).
- If necessary, 20%-PHMB solution can be pre-diluted in water with limited individual Protection Equipments (gloves & protective glasses) and is quickly soluble in water in all proportions.
- PHMB doesn't violently react with any of the products, that also makes it easy to formulate, even in bulk quantities.
- PHMB is stable to light and temperature and can be stored during at least 2 years (test in progress for a 4-y stability)

Regarding possible impact on the environment

Residual PHMB from an industrial activity (formulation or use of PHMB-based products in industrial environments) is not an issue if it is collected. Indeed, PHMB can be easily treated:

- It can be chemically neutralised by anionic products (soft neutralisation)
- It can be neutralised by oxidation with active chlorine or else (chemical decomposition)

In case of lower PHMB residue in effluents of an industrial activity or from a private use of PHMB-based products, additional studies brought show they will not impact the Sewage Treatment Plants operation, and will not be present in their effluents.

In summary: PHMB should not be considered as a candidate substance for substitution as it should be emphasised that this biocide substance brings some important advantages in its uses:

- PHMB is a serious, efficient and economically viable active substance for uses in numerous applications
- PHMB can be stored with very limited risks
- PHMB can be easily handled with limited risks
- PHMB is easy neutralised before release in the environment, if needed