klöckner pentaplast

Company:

Klöckner Pentaplast Europe GmbH & Co. KG
Industriestraße 3-5
56412 Heiligenroth
Germany

Subject:

Comments For Public Consultation MDRM

- **Information on Use, Alternatives, Exposure and Risks**

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Comments on the Wide Dispersive Uses:
As downstream users of the reaction mass of DOTE and MOTE (MDRM), we confirm that we use MDRM in an industrial setting only. We are not aware of any use of MDRM outside an industrial setting by professionals or consumers.

We confirm that our products fulfill the article definition under REACH. Any use of our products are part of the article life.

Comments on the likelihood of the release during article service life and waste phase:
We as the downstream users of MDRM agrees with the following statement:

In order to continue to stabilize the articles throughout its life-cycle stabilizers must not be washed off from the articles. Therefore those molecules are designed to have inherently low leaching rates and this is the case for octyltins which have a very low water solubility (high Octanol/Water partition coefficient). Moreover, MDRM are used extensively in rigid PVC films for food-contact and comply with the applicable Specific Migrations Limit of 6 µg/kg food, which confirms the low leaching rate in aqueous media. For many years in the USA, MDRM based stabilizers have complied with the strict guidelines set out by NSF/ ANSI 61 standards for use in drinking water applications.

Like all additives, leaching in contact with water is limited to a thin diffusion layer and does almost not affect the bulk of the material. This has been demonstrated indirectly by measuring the residual concentration of a tin stabilizer throughout the 6 mm wall of a 22-year old water pipe dug out. The depletion of tin was observed in the 1.5 micron boundary layer, representing 0.05 % of the pipe volume, whilst no depletion was observed in the bulk.

It is therefore the commentator's conclusion that it is unlikely for the release of MDRM during the article service life and waste phase. Additionally after many decades of use in these applications we are not aware of any reported adverse impact on users of articles containing MDRM.

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Comments on the Technical Feasibility of Calcium-based stabilizers as a substitute for MDRM:

Section 10.4 of the Annex XV dossier mentions Calcium/Zinc-based stabilizers as a substitute for MDRM. After extensive testing and formulation work, we have not been able to find an adequate technical substitute that is based on Calcium/Zinc to date.

Sincerely Yours,
Klöckner Pentaplast Europe GmbH & Co. KG

i. V. i. A.

Bernd Schmidt Michael Otten

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