

# REACH perspective under dossier evaluation on a sediment assessment of a NONS substance

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## Regulatory context

For a substance notified under Dir 67/548/EEC the MSCA requested to conduct a panel of tests in order to assess its properties such as fate, bioaccumulation and/or ecotoxicity. The main environmental compartments to be tested were the aquatic, soil and sediment including some tests on bioaccumulation. The Final Decision from the MSCA was handed over to REACH and the dossier update to be evaluated under Art135(1), following the same rules as apply for a follow-up of REACH Testing proposal or Compliance Check decisions.

## Substance profile and Aquatic toxicity data

- organic, mono constituent substance
- WS ca 0.102 mg/L, Log Kow > 4.06 and Log Koc = 4.23. No hydrolysis
- Persistency : not readily nor inherently biodegradable in water. No data on sediment or soil biodegradation -> **P**
- Bioaccumulation: Fish bioaccumulation test and Earthworm test -> **not B**
- Toxicity: No toxicity in acute aquatic toxicity tests and from long term aquatic tests narcotic effects, only observed in *Daphnia*, could be associated with dietary exposure. Trigger for soil and sediment toxicity testing.

### Sediment toxicity

#### OECD 218 :

Range finding test for concentrations: 0, 10, 100 and 1000 mg/L and limit test performed on 1000 mg/L with solvent and control.

In the limit test and range finding test : neither mortalities nor sub-lethal effects were seen on the Chironomids

NOEC= 1000 mg/Kg dry weight sediment nominal

#### OECD 225,

Concentrations tested: 10, 32, 100, 320 and 1000 mg/Kg dry weight sediment.

Test performed on artificial sediment with a solvent.

NOEC = 100mg/Kg dry weight sediment nominal

LOEC = 320 mg/kg growth and reproduction

Toxicity found for oligochaetes but not statistically significant.

### Soil toxicity

#### OECD 222 :

Concentrations tested: 10, 32, 100, 320 and 1000 mg/Kg dry soil artificial solvent and control.

NOEC= 100 mg/kg dry weight soil nominal

LOEC= 320 mg/kg mortality

EC50 > 259 mg/kg for reproduction

Toxicity found for Earthworm with NOEC =100 mg/Kg dry weight

Plant terrestrial tests do not show toxicity at limit concentration so 1000 mg/kg dry weight soil nominal



## Findings

Both Oligochaetes tests in sediment and soil have shown the same results NOEC= 100 mg/Kg dry weight, in both cases organisms were exposed via food chain or dietary exposure/ingestion whether for Chironomus test, the recommendation from the guideline for initial food introduction to ensure exposure to the substance was not followed so lack of toxicity could be related to lack of exposure.

## Outcome

Considering the substance properties and aquatic toxicity results, MSCA instead of considering the EPM to apply for sediment and soil compartments requested the soil and sediment tests.

Based on the low aquatic toxicity and on results obtained with soil and sediments testing, the toxicity should be associated to exposure via ingestion and not to pore water or water exposure, which is consistent with the results obtained in the OECD 218 considering the bias of no food exposed with the substance as advised in the test protocol. The soil test OECD 222 and sediment test OECD 225 performed with Oligochaetes feeding on soil and sediments show the highest toxicity with mortality but also with observed effects on growth and reproduction quantified with specific LOEC.

## Challenge

If the main exposure route is suspected not to be via the aquatic pathway, then the testing on sediment and soil need to be considered using furthermore the substance properties: Log Kow, log Koc, degradability (abiotic and biotic) and WS. This strategy of toxicity testing shall be preferred to aquatic toxicity tests and incorrect application of EPM approach for exposure and risk assessment under REACH.