

An evaluation of studies on nano TiO₂ fate and ecotoxicity for risk assessment – experiences from the OECD Sponsorship Programme

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1. Introduction

In November 2007, the OECD's Working Party on Manufactured Nanomaterials (WPMN) launched a Sponsorship Programme involving OECD member countries as well as non-member economies and other stakeholders, to pool available expertise and fund the safety testing of specific Manufactured Nanomaterials (MNs). In launching the Sponsorship Programme, the WPMN agreed upon a priority list of 14 MNs selected for testing which are in, or close to, commerce. It also agreed upon a list of endpoints for which the selected materials should be tested. Much valuable information on the safety of MNs can be derived by testing this representative set for human health and environmental safety.

In the last years many projects were launched world-wide. Experiments are often performed using standardised ecotoxicological test guidelines that include various optional experimental settings, e.g. test media, which may affect the results. In addition, individual modifications of the test guidelines or individual test procedures have been applied in order to achieve higher effects or include further endpoints. The quality of the available test results and reports determines the accuracy of the risk assessment of nanomaterials. The aim of the presented study was to evaluate the reports and results described for the TiO₂ materials that were selected for the OECD Sponsorship Programme, that characterise their fate and effect in the environment.

2. Materials and methods

Based on the TiO₂ materials selected for the OECD Sponsorship Programme and the requirements according to REACH, a step-wise procedure was applied:

1. Literature review: data were considered when demonstrating results for particles that belong to the TiO₂ nanomaterial batches provided for the OECD Sponsorship Programme, or for the materials used for the OECD Sponsorship Programme but not for the selected batch of the respective material, e.g. for Hombikat UV 100 but not NM-101.
2. Short description of the relevant literature using selected headings of the IUCLID database and NanoHub database respectively, and evaluation of reliability. A modification of the Klimisch Code [1][2] was applied to classify the publications according to reliability. The modified code is described in reports by ECETOC.
3. Summary of the evaluated studies in tabular form using selected parameters of the study descriptions, and classifying the studies according to their suitability for risk assessment (three classifications were applied - suitable / supporting information / less suitable). Due to the limited information available for TiO₂ and nanomaterials ecotoxicity in general, publications of lower quality compared to the assessment of conventional chemicals within the regulatory context were also recommended for consideration.
4. Conclusions: general conclusions on the scope of testing, the sensitivity of test organisms and endpoints, on the suitability of additional endpoints and on the robustness of the test procedures were drawn based on the extracted information.

3. Results and discussion

It was obvious that information on the environmental fate and effect of TiO₂ nanomaterials is still limited. In total 58 publications were evaluated covering 148 ecotoxicological endpoints and 27 studies of fate. The most data was available for the principle material Aeroxide[®] P25 (JRC NM105, respectively).

4. Conclusions

- Deviations from test guidelines:
Many studies show deviations from the guidelines, e.g. different endpoints, incubation periods, or age of test organisms. As the deviations can affect the toxicity, some results are difficult to compare.
- Ecotoxicological effects :
 - Observed Effects: effects are observed in both the terrestrial and aquatic environments. A comprehensive risk assessment should consider both environments, so long as the overall information remains limited. Information requirement under REACH is based upon the annual production volume of TiO₂. Based on these results, this approach is considered less suitable for nanomaterials, especially as accumulation in the terrestrial environment cannot be excluded.
 - Sensitivity of test organisms: aquatic invertebrates and algae seem to be important for ecotoxicological testing with TiO₂ nanoparticles in the aquatic environment. Aquatic sediment organisms are less sensitive to Aeroxide[®] P25 . For the terrestrial environment, invertebrates (earthworms), microbial nitrifiers and plants were determined as sensitive test organisms for indicating toxicity.
 - We expect that the sensitivity of the test species depends on the tested TiO₂ nanomaterial. Therefore, further restriction of the standardised test organisms is not recommended.
 - Sensitivity and recommendations of endpoints: examination of the sensitivity of the different standardised endpoints found no difference for the investigated TiO₂ nanomaterials from those observed for conventional chemicals.
 - Robustness of test procedures: the available information is not sufficient for comments to be made on the robustness of the test guidelines. Round robin tests are needed and their initiation is recommended.
- Test media:
Agglomeration behaviour and zeta-potential of the nanomaterials is dependent on the test conditions. Therefore, it is necessary to clearly specify the test medium used in order to reduce the variability of test results. Defined mineral media and comprehensively described soils may be preferred to tap water, artificial soil, or roughly described soils.
- Additional endpoints for ecotoxicity:
Populations of soil organisms and soil functions (nutrient cycling) shall be protected. Therefore, suitable test parameter are to be considered as additional endpoints if they provide respective information for an adequate risk assessment.
- Characterisation of nanomaterials in test suspensions:
The applied media, time points of characterisation, as well as methods for characterisation and test designs are too variable to serve as basis for an evaluation. More precise specifications of the test methods and procedures applied must be provided.

5. References

- [1] Klimisch HJ, Andreae M, Tillmann U. 1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. *Regulatory Toxicology and Pharmacology* 25:1-5.
- [2] ECETOC JACC Report No. 51. 2006. Synthetic amorphous silica. ISSN-0773-6339-51.

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