

P17. BIOCIDAL PRODUCT APPLICATIONS AND TECHNICAL ISSUES IN EU

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Antifouling paints are Product Type 21 in EU's Biocidal Products Directive. There are ten active substances in the review process and two new active substances available for this product type. Most antifouling paints contain dicopper oxide (or copper thiocyanate), and the BPR application submission deadline for these is expected to be 31 December 2017.

GLP is not required for phys/chem studies, but the laboratory must be certified to an international standard (for example ISO 9001 – Quality management).

Storage stability studies must demonstrate that the active substance content is stable for the claimed shelf life. The decrease should normally not be more than 10 %.

All major antifouling paint manufacturers conduct efficacy studies themselves. Panels coated with the antifouling paint are submerged in the sea for minimum six months. The fouling must be less than on an uncoated panel. Normally the coverage of macro-fouling should be less than 25 %.

There is no need to conduct toxicity or ecotoxicity studies on the antifouling paint. The calculation method in CLP can be used to decide the classification (pictograms and H/P-phrases).

Dermal absorption is a critical in-put parameter for antifouling paints in the human health risk assessment. No antifouling paints will pass the assessment with the default dermal absorption values (25 or 75 %) so studies are needed. Unfortunately today's guidance (EFSA 2012) is not suitable for antifouling paints. This issue needs to be resolved before the submission deadline.

MAMPEC (Marine Antifoulant Model to Predict Environmental Concentrations) should be used to estimate the PEC (Predicted Environmental Concentrations) in water and sediment, both inside and in the surroundings of marina and commercial harbour.

The protection goals set by the member states will decide if efficient antifouling will be available for their shipyard industry and consumers in the future.