Zinc oxide is used extensively in coatings intended for use on the underwater hull area of commercial vessels and pleasure craft, in both non-biocidal and biocidal products. The implementation of the Biocidal Products Directive (98/8/EC) and its associated legislature has resulted in confusion as to the regulatory status of zinc oxide when used in these products.

The adoption of 1451/2007/EC by the member states of the EU has been at the centre of the confusion in that it lists those active substances that were notified as being on the market prior to the 14th May 2000 (Annex 1) and those active substances currently under review as part of the BPD evaluation programme (Annex 2). Zinc oxide was listed in Annex 1 of 1451/2007/EC as an existing active substance on the market prior to 14th May 2000 and zinc oxide does not appear on Annex 2 as an active substance currently under review, suggesting that zinc oxide is a non-supported active substance which should not be placed on the EU market.

However, for product type 21 (PT21), antifouling paints, this interpretation is incorrect. 1451/2007/EC consolidates previous review regulations and notifications relating to changes in the review programme of 98/8/EC. The decisions that were made in previous review regulations and withdrawals of active substances from the review programme have only been summarised in 1451/2007/EC. Directive 1451/2007/EC only lists withdrawn actives but does not define to which product type those actives were associated according to the earlier review regulation 2032/2003/EC. In 2032/2003/EC zinc oxide is identified in Annex 2 (active substances under review) as an existing biocide only for use in product type 8: wood preservatives.

Zinc oxide was never listed in 2032/2003/EC as an active substance in PT21, antifouling paints, as it is not used as an active substance and has never been used as an active substance in those products. Zinc oxide is, however, used in antifouling paints for a number of other reasons which include:

- To control the film polishing rate
- To stabilise the wet paint in the can
- To protect dry films from Ultra Violet (U.V.) damage
- To pigment the system (whiten and hide darker compounds)

Following the withdrawal of zinc oxide from the review programme by the participant (supplier of zinc oxide) a notice was released on the 23rd of March 2004 by the Directorate-General Environment declaring that zinc oxide was withdrawn from the review program as a wood preservative, PT8. **Therefore zinc oxide cannot be used as a biocide in wood preservative products, PT8, which came into force on 1st August 2006. This does not affect the use of zinc oxide in PT21 antifouling paints.**

Zinc oxide was not declared as an existing active substance in PT21, antifouling paints, according to Annex II of regulation 2032/2003/EC as it is not used as such in antifouling paints. **Therefore, when used in PT21 antifouling paints zinc oxide has to be considered as a soluble pigment and not as an active substance or biocidal product according to the definition within Article 2 (a and d) of 98/8/EC:**
2\textsuperscript{nd} September 2011

a \hspace{10pt} \textit{Biocidal products}

“Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.”

d \hspace{20pt} \textit{Active substance}

“A substance or micro-organism including a virus or a fungus having general or specific action on or against harmful organisms.”

Accordingly zinc oxide does not need to be declared on the label as an active ingredient.

Zinc oxide does however carry the environmental classification N;R50/53 (CLP: H400 + H410),\textsuperscript{1} and must therefore be declared on the SDS if present at or above 0.1%. The EU risk assessment (2008) concluded that zinc-containing products were not to be seen as leading to a risk for the aquatic environment.

\textsuperscript{1} REACH registration dossier 2010, CSR