TEMPLATE

for third party submission of information on potential candidates for substitution

NON-CONFIDENTIAL

Legal name of submitter(s): TROY

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1. ALTERNATIVE IDENTITY AND PROPERTIES

There are few fungicides on the market suitable for PT7, PT9, PT10 applications, with only 5-6 appropriate for PT7: (Folpet, conazoles, IPBC, Zinc pyrithione, DCOIT& OIT). Only some have been through the review process but most have not. Therefore, it is unclear what the regulatory status of most fungicides is. All of these mentioned actives demonstrate efficacy but the difficulty is always to understand when to use one compared to another. Every substance has specific characteristics, which means in general, most biocidal products for PT7 contain more than one fungicide. Carbendazim for example is often used in combination with IPBC or OIT and with algaecides.

Several issues with fungicides must not to be forgotten, such as the potential for development of resistance, instability in or incompatibility with the application matrix, for example, discoloration or degradation. Hence the need to keep a reasonable number of suitable actives on the market. Furthermore, it is much more difficult to have fungicides available for a PT7 biocidal use than for a crop protection use. Indeed, the search for the appropriate substance to be used in combination with many others is delicate. In crop protection the fungicide formulation as such is applied in the fields directly onto the crops, whereas the dry-film preservative formulation is not applied directly on to walls, but into complex coating formulations. As a result, no real new active has been put on the market during the last 20 years. Those which have reached the market were only derivatives of existing compounds.

2. TECHNICAL FEASIBILITY

Every dry-film preservative must satisfy a series of criteria to be considered by the paint industry for incorporation. The substance must:

- Be efficient against the target organism(s) at the coating surface (there are thousands of different species of fungi and not every substance is efficient against each in a similar manner) – this is why most biocidal products for PT7 contain more than one fungicide (different active ingredients are blended together in order to give a broader spectrum of activity)
- Be compatible with the coating material (*i.e.* some substances can only be used in solvent based coatings),
- Be colorless, odourless, non-volatile,
- Have a low solubility in water
- Be stable at alkaline conditions
- Be stable in hot and/or humid environments
- Be stable against UV radiation

All these technical conditions are important and must be assessed separately. For instance, the increasing use of water-based paints which have a high pH leads to conditions that cause the degradation of fungicides that hydrolyze in water. Carbendazim is, for instance, very stable at high pH and has a very low water solubility (8 mg/l). This property reduces its leaching potential and one of the major consequences of carbendazim's low water solubility is that it

ensures the effectiveness of the fungicidal protection over a longer period of time. Another important consequence is that this reduces the release of the substance into the environment.

3. ECONOMIC FEASIBILITY

Because there are only a few suitable fungicides that can be used as biocides, it is very difficult for the industry to formulate alternatives. New fungicidal actives are only sought in a few industries like pharma, and crop protection with a very different property profile and possibility of transfer to film preservation applications is extremely low. Moreover, the biocides market is so small in general and in particular for PT7 (€ 50 million) that it is too costly for a biocides company to develop a new substance (around € 200 million) and it would take years before such new substance is discovered (10 in average). Under this scenario, the return on investment would be too low and the commercial risk would be too high.

In other words, should a company lose the registration of its substance, it would run major commercial risks, since looking for alternatives matching the formulations of its existing client base would be very challenging, especially in hard economic times where the demand for coatings has decreased in the past 5 years.

Changing to a new film preservative at a paint company is a time consuming and difficult task. Every paint company works with its own formulations, made of various chemicals. They buy carbendazim based preservatives because they know, since the last 20 years that carbendazim, apart from being stable at high pH and not soluble in water, is compatible with the coating material and the colorants. This offers the desired freedom in development of new coating formulations and ensures product differentiation The need to consider fungicide stability and compatibility during coating development makes the development work extremely complex.

It is also important to note that the BPR has also increased substantially the registration costs reinforcing unfortunately the above economic consideration.

Damages to the dry-coating by microbes will lead to discoloration, degradation, loss of economic value of the real estate and in the case of indoor coatings, may cause allergies and sickness. Consumers wish therefore that the paint they buy be efficient and at a reasonable cost. In this sense, it is worth noting that biocides represent between 2 to 20% of the cost of the paint. Given that it is substantial, paint producers seek the best quality-price ratio. The film preservative with a well-established track record also allows most paint producers to offer a guarantee which can be up to 5 years or longer.

4. AVAILABILITY

As stressed, given that there are only very few fungicides on the market, it would be problematic for the market to lose any active substance. All fungicides are available in volumes required to support the market but this is not a relevant consideration. The main issue is whether technically and economically, the alternatives are appropriate.

5. CONCLUSION ON SUITABILITY AND AVAILABILITY OF THE ALTERNATIVE

The number of fungicides currently available in the market is limited. Few of these are stable at high pH – a requirement for water based decorative coatings. A number of the alternatives in the market have high water solubility, which leads to rapid release from the coating into the environment. Very few of the available fungicides have completed the review process, so limiting the choice of fungicide before completion of the evaluation process would be a mistake.

6. OTHER COMMENTS

The coatings market requires fungicides and the fact that it can rely on 5-6 substances is positive. Less would definitely create difficulties in the paint industry and there is no perspective that more actives will come onto the market shortly. On the contrary, the pressure on the crop protection industry through the exclusion criteria, as defined in the Regulation 1107/2009 and the uncertainty around the definition of endocrine disruptors will probably reduce the number of actives and therefore also reduce the likelihood that some could be used in biocidal products.