



Risk Assessment of Malakite with the Active Substances Dithianon and Pyrimethanil

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Authors' contributions

This work was carried out in collaboration among all authors. The opinion has been assessed and approved by the Panel on Plant Protection Products of VKM. All authors read and approved the final manuscript.

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Grey Literature

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ABSTRACT

The plant protection product Malakite (BAS 669 01 F), containing the active substances dithianon and pyrimethanil, is a fungicide against scab in pome fruits. Products containing these active plant protection substances are approved in Norway, but not with both substances in the same product. The Swedish Chemicals Agency (KemI) has as zonal Rapporteur Member State (zRMS) of the

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Northern Zone evaluated the product Malakite and decided on non-approval due to the observation of unacceptable effects in exposed birds, aquatic organisms, non-target arthropods and earthworms.

On request from The Norwegian Food Safety Authority, the VKM Panel on Plant Protection Products has discussed the available data and the report prepared by Keml, and has concluded as follows on the questions raised:

On the refinement of DT50 in long term risk assessment for birds:

It is the view of the VKM panel that the refinement is not acceptable because the analysis using first order kinetics seems not in line with a realistic and sufficiently conservative approach for the data provided. Furthermore, field studies from more sites are required.

On the long term cumulative effects of the active substances on birds:

VKM shares the view of Keml, that the combined sub-lethal and reproduction effects should be assessed because the mode of action of the two ingredients has only been shown in fungi, and since the mechanisms in birds could be different.

On the reduction of assessment factor for fish:

VKM opposes to the reduction of assessment factor for dithianon in fish because the data from acute toxicity tests cannot be extrapolated to chronic toxicity, and because the factor should reflect not only the variation in interspecies sensitivity, but also the uncertainty involved in extrapolation from laboratory tests to the field situation.

On the choice of end point in risk assessment for fish:

The VKM panel considers the NOEC of dithianon for fish determined from the study at pH 7.9 not to be adequate for the more acidic Norwegian surface waters, and recommends using the data from the test performed at pH 6.5.

On the formulation studies for aquatic organisms:

It is the opinion of the VKM panel that the formulation studies may be used together with corresponding studies with the active ingredients as long as the studies compared are performed and evaluated according to the same principles. However, VKM notes that the formulation tests as well as the tests of the active ingredients have been performed at high pH values, which are not representative to most Norwegian surface waters. Thus, the toxic effect of dithianon shown in these tests are likely to be lower than expected under typical conditions in Norway.

On the assessment factors for concentration addition in fish:

It is the opinion of the VKM panel that a reduction in assessment factor for one component in a mixture cannot be used for a formulation containing components for which a similar reduction has not been accepted.

On effect studies of active substances and formulations on non-target arthropods:

The VKM panel shares the view of Keml that the risk assessment should be based on all available information, including the studies presented for the active substances.

On the endpoint in earthworm risk assessment:

VKM supports the view of Keml that the observed effects of pyrimethanil on reproduction of earthworms should be considered in the risk assessment of Malakite.

Keywords: VKM; risk assessment; Norwegian Scientific Committee for Food Safety; Malakite; pesticide; dithianon; pyrimethanil.

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NOTE:

This work was carried out in collaboration between all authors. The opinion has been assessed and approved by the Panel on Plant Protection Products of VKM. All authors read and approved the final manuscript.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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