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INCLUSION OF CHEMICALS IN THE INTERIM PRIOR INFORMED CONSENT PROCEDURE - SUPPORTING DOCUMENTATION

Vinclozolin

Note from the Secretariat

1. Annexed to this note is the documentation provided by Norway in support of their notification of final regulatory action on vinclozolin.

* UNEP/FAO/PIC/ICRC.5/1
Supporting documentation on vinclozolin from Norway:

English summary of Danish report from 1993
VINCLOZOLIN

Økotoksikologisk evaluering

Baggrundsrapport

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B. SUMMARY

Application has been made for approval of the use of Vinclozoline (3-(3,5-dichlorophenyl)-5-methyl-5-vinyl-1,3-oxazolidine-2,4-dione) as a fungicide in Denmark. In the report the ecotoxicological properties of the substance have been evaluated.

Vinclozoline is only slightly adsorbable to soil. In a test adsorption coefficients (Kₐ) of 0.6 to 9.6 have been determined. As, however, vinclozoline has a poor water solubility it is estimated that the risk of leaching under normal weather conditions is rather limited.

The standardized leaching tests made are not unambiguous. In one test with 3 standard soils no vinclozoline nor metabolized products were found in the eluate. In another test, however, a leaching of ¹⁴C from radioactive-labelled vinclozoline was observed, 2.5% being in a sandy soil and 0.2% in a loamy sand soil. Finally a leaching test was made after an initial incubation of vinclozoline for 30 days. The leaching of metabolized products or intact vinclozoline in two loamy sand soils was 3% and 10% respectively of the radioactivity added. No supplementary leaching tests have been made under field work conditions.

Evaluated on basis of the Henry law constant the vinclozoline is not expected to evaporate from soil nor water. This evaluation is supported by the metabolism tests made.

In tests of the hydrolysis stability it has been observed that vinclozoline is easily hydrolysed in a strongly alkaline aqueous environment (pH 13). As these tests only lasted for 24 hours, it is not possible to evaluate the hydrolysis stability found of 100% at pH 6-8. Photolysis is evidently to stimulate the primary metabolism of vinclozoline in soil.

Tests of the aerobe metabolism in soil with radioactive-labelled vinclozoline demonstrate identically that the substance is only partially metabolized into chlorinated metabolized products. The total radioactivity in the soil was constant throughout the test period (60-240 days), and the generation of carbon dioxide from ¹⁴C-labelled vinclozoline made out only approx. 1% of the quantity added. The metabolism of vinclozoline resulted in an accumulation of the product 3,5-dichloranilin which is presumably bound to humus. It is considered that 3,5-dichloranilin will be slowly degradable in soil and water,
as can already be seen from the constant total radioactivity in soil samples incubated for up to 240 days.

A corresponding primary metabolism of vinclozolone has been demonstrated in metabolism tests with anaerobic soil samples, but as there is no safe indication of a deoxidized environment, the result can not be used as an expression of anaerobic degradation of the substance.

The n-octanol/water-partition-coefficient (\(P_{ow}\)) is determined to 1054 ± 435 corresponding to a log \(P_{ow}\) of 2.79 to 3.17. Based on this vinclozolone must be evaluated to have a potential for bioaccumulation in aquatic organisms.

The tests performed on plant metabolism indicate that metabolism/degradation occurs of most of the vinclozolone applied to non-identified polar metabolites (conjugates) containing a dichloraniline fraction as well as to the metabolites stated in figure 4. The test results indicate further that vinclozolone is not mineralized in strawberry and lettuce plants. At the tests were 31.4% (strawberry) and 3.3% (lettuce) of the total \(^{14}\)C remaining identified as vinclozolone about one month after the last application.

In a bioaccumulation test on fish with aerobically aged vinclozolone (originally \(^{14}\)C-vinclozolone equivalents), bioconcentration factors of 2.3-11 (whole fish); 1.0-4.5 (edible fraction) and 3.5 to 15 (non-edible fraction) were found. Through elimination more than 97% of the highest measured concentration of \(^{14}\)C-vinclozolone in the fish were separated in 3 days. The bioaccumulation potential of vinclozolone is therefore considered to be limited.

The LC50(14 days) to earthworms is determined to be > 1000 mg a.i./kg soil (DM) and the NOEC(14 days) to 1000 mg a.i./kg soil (DM).

The NOEC to soil respiration is estimated to be < 10 mg a.i./kg soil (DM).

The NOEC to ammonification is estimated to be 50 mg a.i./kg soil (DM).

The NOEC to N-fixation is estimated to 50 mg a.i./l growth medium (Azotobacter chroococcum).

The LD50 for quails is determined to > 2420 mg a.i./kg body weight (NOED = 965 mg a.i./kg body weight). The LC50 for quails is determined to > 5420 mg a.i./kg fodder (NOEC = 3050 mg a.i./kg fodder). The LC50 for mallard is determined to > 5420 mg a.i./kg fodder (NOEC = 5420 mg a.i./kg fodder).
At a reproduction test with mallards no exposure related effects could be demonstrated. The NOEC (birds’ reproduction) is estimated to 50 mg a.i./kg fodder.

In a test of the effect of vinclozoline on the growth of single-celled green algae the EC50(96 hours) is determined to be 16 mg a.i./l and the NOEC(96 hours) to 1 mg a.i./l.

However the test results are evaluated to be of poor reliability and the test results will not be included in the final ecotoxicological evaluation of vinclozoline.

Through a static test (48 hours) of the acute toxicity of vinclozoline to daphniae the LC50(48 hours) was determined to 4 mg vinclozoline/l and the NOEC(48 hours) to 1 mg vinclozoline/l. At a reproduction test to daphniae the LC0 (21 days) was determined to 7.8 mg vinclozoline/l and the EC0(21 days, reproduction) to 1.95 mg vinclozoline/l. The NOEC is estimated (based on the given size of the daphniae) to 0.98 mg vinclozoline/l. All given concentrations are nominal.

The LC50(96 hours) to Bluegill Sunfish (Lepomis macrochirus) is determined to 47 mg vinclozoline/l and the NOEC(96 hours) to < 5.6 mg vinclozoline/l. LC50(96 hours) to rainbow trout is determined to > 18 mg vinclozoline/l and the NOEC(96 hours) to 1.8 mg vinclozoline/l. All given concentrations are nominal.