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## **Risk Assessment of the Pesticide Centium with the Active Substance Clomazone**

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### **Authors' contributions**

*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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### **ABSTRACT**

Centium is a new product in Norway containing the active substance clomazone. The product is applied for use as a herbicide in potato, carrot, cabbage, brussel sprout, swedes, oil seed rape, pea and bean. The Norwegian Institute for Agricultural and Environmental Research recommend approval in potato, carrot, swedes and pea. They do not recommend approval in oil seed rape, cabbage and bean because of lacking documentation on efficacy. The Norwegian Scientific

Committee for Food Safety (VKM) was asked by the Norwegian Food Safety Authority to perform a risk assessment on human health and environmental fate of the active substance and the product. The risk assessment of the product was finalized at a meeting May 18, 2011, by VKM's Scientific Panel on plant protection products (Panel 2). VKM Panel 2's conclusion is as follows:

The active ingredient clomazone is of moderate acute toxicity after oral and inhalation exposure and of low dermal toxicity. The product Centium is of low acute toxicity after oral exposure, by skin contact or by inhalation; however the product may contain a co-formulant, monomeric isocyanate, with sensitizing properties. Due to the lack of documentation on the monomer content, the Panel cannot evaluate the risk of sensitization. UK Poem model estimation of exposure show that exposure to operator is below AOEL and the health risk is therefore minimal.

The effects observed in the dog study were considered due to the exposure of clomazone and should therefore be used to determine the NOAEL value.

The fertility index used in the two-generation study in rats is not considered relevant as a measure of critical effect. The Panel suggests to use 4000 ppm (354 mg/kg bw/day) which is the highest dose tested in the study.

Dose dependent responses were not always evident in the rat teratology study, but significant effects were found at the two highest dose levels (300 and 600 mg/kg bw/day). The observed effects were considered adverse. The proposed NOAEL of 100 mg/kg bw/day was therefore supported.

The teratology study with rats is considered relevant for determination of acute reference dose (ARfD) since skeletal malformations can be induced after short exposure periods if the exposure is taking place during a sensitive period of foetal development.

The Panel also concludes that based on the results from modeling with MACRO (4.4.2) using the Nordic groundwater scenarios and the input parameters agreed upon in the EU there is a potential for contamination of groundwater exceeding the trigger value of 0.1µg/L for the active ingredient following prescribed usage.

*Keywords: VKM; assessment; Norwegian scientific committee for food safety; centium.*

Available:<https://vkm.no/download/18.3a33d0ea16122420c393db60/1516971316218/Risk%20assessment%20of%20the%20pesticide%20Centium%20with%20the%20active%20substance%20clomazone.pdf>

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## **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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