



Risk Assessment of the Plant Protection Product PROMAN – with the Active Ingredient Metobromuron

**Marit Låg^{1*}, Hubert Dirven¹, Jan Ludvig Lyche², Asbjørn Magne Nilsen³,
Katrine Borgå⁴, Ole Martin Eklo⁵, Merete Grung⁶, Line Emilie Sverdrup⁷
and Torsten Källqvist⁸**

¹Norwegian Scientific Committee for Food Safety (VKM), University of Oslo, Norwegian Institute of Public Health (FHI), Norway.

²Norwegian Scientific Committee for Food Safety (VKM), Norwegian University of Life Sciences, Norway.

³Norwegian Scientific Committee for Food Safety (VKM), Norwegian University of Science and Technology, Norway.

⁴Norwegian Scientific Committee for Food Safety (VKM), University of Oslo, Norwegian Institute for Water Research, Norway.

⁵Norwegian Scientific Committee for Food Safety (VKM), Norwegian University of Life Sciences, Norwegian Institute for Bioeconomy Research, Norway.

⁶Norwegian Scientific Committee for Food Safety (VKM), Norwegian Institute for Water Research, Norway.

⁷Norwegian Scientific Committee for Food Safety (VKM), University of Oslo, Det Norske Veritas, Norway.

⁸Norwegian Scientific Committee for Food Safety (VKM), Norway.

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.

Article Information

DOI: 10.9734/EJNFS/2019/v11i230139

Grey Literature

**Received 28 July 2019
Accepted 31 October 2019
Published 19 November 2019**

ABSTRACT

Proman is a new product containing the active substance metobromuron. The intended use is as a broad spectrum selective herbicide for potatoes grown outdoors.

VKM's Panel on Plant Protection Products has discussed the questions raised by The Norwegian Food Safety Authority in the Terms of reference and has stated the following opinion:

*Corresponding author: Email: tron.gifstad@vkm.no;

On the relevance of the carcinogenic effects observed in the rat carcinogenicity study; fibrosarcomas in females and pheochromocytomas and Leydig cell tumours in males:

It is the opinion of VKM's Panel for Plant Protection Products that the relevance of the observed incidence in mammary gland tumours and Leydig cell tumours in the rat carcinogenicity study is strengthened by the fact that the tumours are observed in hormone responsive tissues. The panel concludes that the carcinogenic effects observed in the rat carcinogenicity study are likely to be relevant for tumours that are influenced by the endocrine system, also in humans.

On the higher incidences of still dumbbell-shaped centres of thoracic vertebrae and nonossification of the 13th rib observed in the rat developmental toxicity study and whether these are considered to be malformations:

VKM's Panel on Plant Protection Products has discussed the classification of the different types of incomplete ossifications and concluded that incomplete ossification of sternbrae and non-ossification of the 13th rib in rats should by itself be considered to be variations, and not adverse developmental effects. On the other hand, the Panel agrees with ECHA that the "thoracic vertebral centres still dumbbell-shaped" should be considered as malformations, due to limited data and understanding of the mechanism underlying the observed slow reversal of these anomalies. Furthermore, it is the view of the Panel that the different types of retarded ossification induced by the exposure of metobromuron should be considered as a whole when assessing for developmental effects.

On the establishment of the NOAEL for the developmental toxicity study in rats and the reference value (ARfD):

VKM's Panel on Plant Protection Products supports the proposal of an ADI value of 0.008 mg/kg bw/day based on a NOAEL of 0.8 mg/kg bw/day from the 2-year study in mouse, and VKM Report 2015: 03 5.

AOEL of 0.016 mg/kg bw/day based on the NOAEL of 1.6 mg/kg bw/day from the 1-year feeding study in dog. An UF of 100 is applied. The panel suggests on the other hand an ARfD of 0.03 mg/kg bw based on a LOAEL of 10 mg/kg bw /day with the observations of incomplete ossification in the rat developmental study. An UF of 300 is applied.

On the possible anti-androgenic potential of metobromuron:

It is the view of the Panel that the rat carcinogenicity study suggests that metobromuron may possess endocrine disrupting potency. The data from the Hershberger in vivo rat study and the in vitro studies is also suggestive of a weak anti-androgenic effect. Thus, it is the opinion of the VKM Panel on Plant Protection Products that an anti-androgenic effect of metobromuron cannot be excluded.

Keywords: VKM; risk assessment; Norwegian Scientific Committee for Food Safety; pesticide; metobromuron; Proman.

Available:<https://vkm.no/download/18.2994e95b15cc545071614199/1498135127091/3c64afe035.pdf>

ISBN: 978-82-8259-157-7

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.

Competence of VKM experts: Persons working for VKM, either as appointed members of the Committee or as external experts, do this by virtue of their scientific expertise, not as representatives for their employers or third party interests. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

Suggested citation: VKM (2015). Risk assessment of the plant protection product PROMAN – with the active ingredient metobromuron. Opinion of the Panel on Plant Protection Products of the Norwegian Scientific Committee for Food Safety. VKM Report 2015: 03, ISBN: 978-82-8259-157-7, Oslo, Norway. Available online: www.vkm.no.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

© 2019 Låg et al.; This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.