

Fort Dodge Animal Health
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F A C S I M I L E

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Urgent

For your review

Please reply asap

Please comment

Remarks:

Please find attached an amendment to the comments on the TAP Report Review that were provided by Fort Dodge Animal Health.

Fort Dodge respectfully requests that this addendum be added to Fort Dodge's previous comments to the TAP Report Review.

Respectfully submitted,

Deborah T. Chaleff, Ph.D.
Director, Regulatory Affairs

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Proposal to Approve Moxidectin for Use in Organic Production Systems

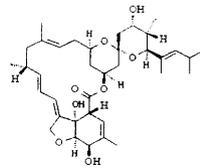
- Moxidectin is produced from fermentation, it is produced by *Streptomyces cyanogriseus* subspecies non-cyanogenus.
- No genetically modified materials or processes are used in its production.
- A methoxime side chain is added to the C23 position of the molecule after fermentation, and there is a purification step to remove extraneous materials to produce high purity moxidectin.

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Production of Moxidectin

Fermentation using *Streptomyces cyanogriseus ssp. noncyanogenus**



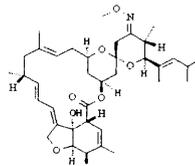
nemadectin



purification



add methoxime group



moxidectin

*a naturally occurring soil organism, not genetically modified

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Moxidectin Is Different from Ivermectin

- **Ivermectin is listed on the approved list of products for organic cattle production.**
- **Both moxidectin and ivermectin are macrocyclic lactones.**
- **Moxidectin has a similar chemical structure and similar antiparasitic activity, but has some significant differences from ivermectin.**
- **The pharmacokinetics in cattle is different – moxidectin has significantly lower tissue levels in cattle than ivermectin.**



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Moxidectin Is Different from Ivermectin

- **The FDA has approved the use of moxidectin pour-on in cattle with zero days withholding period for both meat and milk.**
- **Zero day withholding period claims based on residue data analysis. This analysis predicts that 99% of treated cattle will have residues that are well below levels defined by FDA.**
- **Ivermectin is not permitted for use in dairy cattle because residues are present in milk for a significant period after treatment.**



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Moxidectin Is Different from Ivermectin

- **Unlike the avermectins, residues of moxidectin in the dung of treated cattle will not affect breeding, egg laying, developing stages or adults of dung beetles.**
- **Moxidectin is 64 times less toxic to dung beetle larvae than abamectin.**
- **Moxidectin is permitted for use by Bioland organic production systems in Germany, ivermectin is not.**
- **The National Trust in UK does not permit use of ivermectin in livestock on its properties but does permit moxidectin.**



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Moxidectin Is Different from Ivermectin

- **Delayed degradation of dung from ivermectin treated animals has been reported in many scientific studies.**
 - **decreased available grazing area**
 - **reduced nitrogen recycling into pasture**
 - **decreased pasture nutrient quality**
 - **decreased soil aeration**
 - **decreased water filtration into soil**
 - **water contamination and algal blooms**
- **Studies have shown that dung from moxidectin treated animals degrades at the same rate as that from untreated animals.**



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