

From  
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Copies to  
Dr J R Heylings  
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Your ref	Our ref	Direct line	Tel ext	Date
	SEJ/LMM	0625 512818	2818	26 Apr 91

CTL RECOMMENDATIONS FOR EMETIC INCLUSION LEVELS IN GRAMOXONE

CTL Review Team

I believe it appropriate for CTL to review its data base and recommendations made to the Agrochemical Business for the inclusion level of emetic in paraquat formulations. It is quite routine for us to review our positions from time to time. The Business is currently considering a new emetic plant and clearly inclusion levels could impact on the consideration of the capacity of such a plant. At the same time Dr Smith has left the Laboratory and a new team is accountable for the Laboratory position and representing it within the Business.

Dr Smith has been recommending to the Business for some time that the emetic level in gramoxone should be increased. While it is unlikely that the direction of our recommendation will change Dr Heylings has also made representations to me that the force with which our argument can be put would be increased by a modern review of the data base.

Accordingly I am asking you to lead a small team of Dr Heylings as an emetic and formulation expert and Dr Bob Scott as paraquat Produce Manager to address the issue.

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The remit of the team is to;

1. Review all the pertinent existing data relevant to the selection of the inclusion level of the emetic PP796 in Gramoxone and other Paraquat formulations. The review to include data from the dog and man.
2. To confirm or derive a new recommendation for the Laboratory on the inclusion level of emetic. I require the recommendation to display the likely outcome of several different levels or 'bands' of emetic inclusion together with the advantages and disadvantages of each. I require assurance that there are not upper levels of emetic inclusion which might compromise the patient.

I would emphasize that I wish the review to be comprehensive, constructive and forward looking. This is not a request for a long document, I leave it to you to judge what is required to clarify and support recommendations. The report should be prepared for me. In the interest of economy it may be appropriate that the report is in a form which is eventually suitable for sharing with the Business and conveying our recommendations. However I leave it to you to judge again whether a report to me and to the Business are compatible or not. It may be that a separate report will be required to display the information to the Business in a form that is clear to non toxicologists.

I would like to receive the report by the end of June.



S E Jagers