

CHEVRON CHEMICAL COMPANY
ORTHO DIVISION
RESEARCH AND DEVELOPMENT DEPARTMENT
RICHMOND, CALIFORNIA

CONFIDENTIAL

DATE: OCTOBER 4, 1976

MEETING ON PARAQUAT FORMULATIONS

FILE NO: 721.34/PARAQUAT FORMULATIONS

This meeting was held to discuss strategy regarding the emetic formulation of Paraquat. In attendance were: J. Abell, A. C. Assad, R. D. Cavalli, H. G. Franke, B. F. Quisenberry, J. N. Ospenson, L. R. Stelzer and C. R. Tanner.

Ospenson opened the discussion by presenting background on the emetic material originally researched by the Pharmaceutical Division of PPD. Our purpose is to define a development program agreeable to both R&D and Marketing which can then be presented for Mr. Barlow's approval. PPD is under severe pressure in many areas of the world and, particularly in Japan and Malaysia, to reduce or eliminate the use of Paraquat in human suicides. PPD definitely plans to proceed with the emetic formulation and will make formal application to the U.K. government this month, with plans to initiate sales in the Spring of 1977.

Cavalli reviewed the toxicology data on PP-796; which was given to him on the day of his departure from the U.K. following the liaison meetings the first week in September. The data do not support PPD's contention that 5 mg of PP-796 in 10 ml of formulated product will produce emesis within 15 minutes in 80% of those ingesting such a quantity. The animal and human data made available by PPD would indicate that PP-796 would have to be administered at 2-5 mg/kg and even then the rate of individuals responding and the time to response is such that the survival rate of ingestion cases may not be significantly improved. There are serious discrepancies between the actual data provided and what PPD has been telling us verbally. In light of this information, Ospenson and Cavalli will call Braunholtz the morning of Tuesday, October 5.

Discussions then continued on the basis of two assumptions:

1. The added cost to the product would be about 50¢ per gal.
2. PPD has real data to back up their submission and the effectiveness/safety of PP-796.

It was decided we should submit a package to EPA which would be an exact duplicate of the data which PPD will send to the U.K. government. Our submission to EPA will be a request to register an alternate formula containing PP-796 and asking for an exemption from tolerance when used in Paraquat herbicide formulations at up to .1% weight to volume. We recognize that EPA may raise questions on toxicology and crop residues and, therefore, we will undertake a positive program to fill these potential data gaps. Projected timing would be: first submission to EPA as soon as possible (October/November, 1976), conduct toxicology and residue trials during 1977, resubmit in late 1977, obtain acceptance in mid/late 1978, and initiate marketing in early 1979.

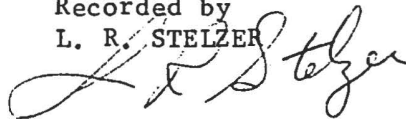
PPD is planning to market their product with the emetic plus stench. We will likewise include the emetic in our stench product, which we expect to have registered by the Fall of 1977. Therefore, we will have two alternate formulae to submit this fall, one with stench and the other stench plus emetic. We will do no further work to develop a color or dye formulation.

Additional discussion centered around a question of whether or not we should announce, via a press conference or other such public procedure, the fact that we have added an emetic to Paraquat. There appeared to be no advantage in making such an announcement.

Ospenson advised that work on the solid formulation will be brought to a close this fall. If, in the future, a decision is made to restart this work, it is recognized that it will take approximately 3 years from startup to the time we could register and produce a solid formulation, the PPD formula being the one of choice at this point.

Further immediate action towards obtaining registration of the emetic formulation will depend upon the information we can obtain from PPD.

Recorded by
L. R. STELZER



LRS:mab

cc: All Attendees