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Toxicity Studies with PCB in Primates

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Among the more critical reasons to conduct a reproduction study with PCB in primates is Monsanto's announced decision to discontinue PCB manufacture. This will be interpreted, by some, as an admission of the uncontrollable hazards associated with PCB. Even though we discontinue manufacture, those materials will not immediately disappear from the environment. Therefore, our liability and responsibility will not terminate when production ceases. Our strongest position will be one supported by an in depth understanding of the health effects of PCB. To be faced with inconclusive information, of which we had prior knowledge, will constitute a very weak Monsanto position.

The results of the Allen study suggest that the sub-human primate is more susceptible to the toxic effects of PCB than are rodents or dogs. These results also suggest that fetal survival in treated females was the most sensitive parameter evaluated. The toxic effects reported were observed at the lowest level (2.5 ppm) tested. Therefore, this report could be interpreted to meaning that any PCB exposure would result in the same response in humans.

The impact of the report of PCB induced carcinogenicity was reduced by our independent review of the histopathologic material from the study. The demonstration of a PCB exposure level that would not have adverse effects on reproduction in sub-human primates can be anticipated to have a similar effect.

It is recommended that a reproduction study be conducted to define a no-effect level. The most qualified facility, as outlined in the attachments is Litton Bionetics. This study would involve 48 sexually mature primates and require 12 to 18 months to complete. The anticipated results would define a no-effect level and support continued Food and Drug Administration guideline for PCB contents in food commodities.

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attachments