Monsanto

FROM (NAME & LOCATION) D. A. OLSON - ST. LOUIS

DATE January 14, 1969

SUBJECT Aroclor Toxicity

REFERENCE

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It has taken some time to develop the information requested in your memo on Bran Oil poisoning. We had indeed heard of the incident, and are desirous of helping you where possible.

I have attached three items for your assistance. The first reviews present toxicological information on Aroclor, and was prepared by our Medical Department. Basically, there are few regulations and little information on human toxicity. This is because we do not envision the use of Aroclor as either a direct or indirect food additive, and have little justification for the expense of the toxicity testing which would be required.

Second, there is a review of our history in the use of Therminol in food industry applications and a discussion of engineering design considerations. This should be of major assistance to you, since it relates the successful application of Therminol in this market and points out that proper design safeguards can be instituted to eliminate any practical hazard.

Finally, attached is our Engineering Design Guide for Therminol systems.

We, like you, are vitally concerned that no Governmental action in Japan be taken which would be harmful to Aroclor. I believe that the enclosed information will alleviate the problem, but please let me know if we can supply anything further.

D. A. Olson

/mh
attachments

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TOXICOLOGY

1. In the U. S. the only "hygienic regulations" referring to chlorinated biphenyls are the Threshold Limit Values (TLV) for Aroclors 1242 and 1254. The values are 1.0 mg/cubic meter of air and 0.5 mg/M^3, respectively. These limits have been set by the American Conference of Governmental Industrial Hygienists, a quasi-official group with no legal authority for establishing Federal standards.

These levels are time weighted averages deemed to be safe for 8-hour daily exposure in industry for a lifetime of work. Although they are intended as guidelines, a number of individual states have considered the TLVs as appropriate for adoption in state codes and regulations. Further, by reference, the TLVs can be enforced by the U. S. Department of Labor in industrial plants subject to the Walsh-Healey contract act.

2. There are no regulations concerning the Aroclors in applications where there might be oral ingestion of these materials. For example, there are no direct food additive or indirect food additive uses approved by the Food and Drug Administration. To our knowledge none of Monsanto's customers have applied for a petition for regulations permitting such use although currently a petition for the use of Aroclor 5460 in adhesives for food packages is in development.

Similarly there have been no applications in the pesticides field where the U. S. Department of Agriculture would have to be consulted.

In the absence of prospective uses which would require such governmental clearances, there has been no incentive to undertake the extensive animal toxicity studies which would provide data necessary for establishing a human diet tolerance.

3. If there were extensive animal toxicity data available, I do not believe the Food and Drug Administration would set a tolerance level in foods where the presence of the chlorinated biphenyl resulted from leakage from a heat transfer system. Such presence would result from a leakage or other accidental contamination and would not be accepted as being "necessary" or adding anything beneficial to a food grade substance.

4. The data or literature concerning effects of chlorinated biphenyls on humans relate only to excessive vapor inhalation or excessive skin exposures. It is not possible at this point to extrapolate from any of the animal toxicity data or human accidental exposures to a "safe" ingestion level for humans.

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5. The chlorinated biphenyls are not "poisons" or "drugs". There are a number of definitions in the U. S. relating to the classification of industrial chemicals and household products. Included are definitions of the Interstate Commerce Commission, the Federal Hazardous Substances Labeling Act, the National Safety Council recommendations, etc. Each of these establishes levels of toxicity and poison categories by the results of specific animal tests. The chlorinated biphenyls would not be classed as "poisons" by any of these definitions. They would be considered "toxic" but no more so than many common industrial chemicals and, as a matter of fact, many formulated products used around the home.

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