

Interoffice Correspondence

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CONFIDENTIAL

Subject: Meeting Minutes - Review
of Animal Studies

cc: R.J. Davis - 220-12E
J.D. LaZerte - 236-1
L.J. Magill - 223-6SE
A.L. Rosenthal - 230-3
T.J. Scheuerman - 220-12E
F.A. Ubel - 220-2E

May 17, 1978

THOSE PRESENT:

M. T. CASE 218-2
J. E. LONG 220-2E
R. A. NELSON 218-3
R. E. OBER 218-2
R. A. PROKOP 236-3B

Those present met on April 28, 1978 to discuss results of the 90 day animal studies carried out at I.R.D.C. The dosing phase of studies on rats using FC-95, FM-3422 and FC-143 have been completed. Dosing of the monkeys on FC-143 is complete while the FM-3422 and FC-95 monkey dosing will be completed in May. An up-to-date status summary of all studies was supplied by J. E. Long and is attached to these minutes. A complete report from I.R.D.C., including histopathological data is due in June or July for the rat studies and later in the fall for the monkey experiments.

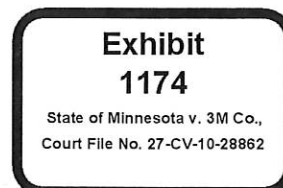
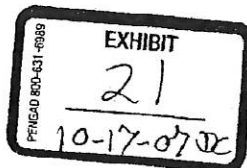
After a very brief discussion of the most recent results from the animal studies, M. T. Case, J. E. Long, R. A. Nelson and R. E. Ober agreed that FC-95, FM-3422 and FC-143 should be regarded as toxic although the degree of toxicity was left undefined.

R. E. Ober inquired as to the types and amounts of impurities present in FC-95, FM-3422 and FC-143. Some impurities, if sufficiently toxic, could cause erroneous conclusion from the animal studies. During the discussion, it was pointed out that FC-95 has been identified in the blood of rats which were fed FM-3422. The question arose as to whether FC-95 might be an impurity in FM-3422. The answer was not known. R. A. Prokop agreed to supply the committee with all available information on impurities present in FC-95, FM-3422 and FC-143.

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R. J. DAVIS



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R. E. Ober raised the question as to which compounds related to FM-3422 and FC-95 would cause greatest worker exposure. Because of the many products related to these compounds, no definite answer could be given. However, because of the large volumes involved, it is believed that FM-3422 itself and FC-807 would contribute most to exposure. It was agreed that Industrial Hygiene should spend more time in identifying the intensity of employee exposure related to FM-3422 and FC-95.

A discussion then took place on analytical methods for determining FC-95 in serum and tissue. Due to the (high?) toxicity of FC-95, it would be advisable to sample the blood of workers exposed to FC-95 or related compounds in order to determine $C_{F11}SO_3$ levels. The analytical method which has been developed for FC-95 is claimed to be sensitive down to a level of 0.5 ppm, however supporting data is lacking. Also, if the method is satisfactory down to a level of 0.5 ppm, it should be adequately sensitive for determining the amount of FC-95 in serum and liver from I.R.D.C. rat studies. However, supporting data are not available. It was concluded that R.E. Ober and R.A. Prokop should meet with Central Research Analytical personnel and analyze the data on determination of FC-95 in serum and tissue in order to assess the reliability of the method.

A discussion then took place on having the capability of analyzing for FC-95 in serum and liver of animals before starting the two year animal studies. R. A. Nelson and J. E. Long felt that FC-95 should be identified as being present before proceeding with the studies since it is possible that a metabolite of FC-95 might be responsible for toxic effects rather than FC-95 itself. R. E. Ober regarded such studies as supplemental. It was agreed that analytical work on FC-95 in the serum and liver of rats should be completed as rapidly as possible.

It was questioned why FC-95, FM-3422 and FC-143 were chosen for the animal studies. FC-143 and FC-95 have been found in the employees. FM-3422 is an intermediate which goes into a variety of products. R. E. Ober suggested that a two year study on FM-3422 would give information on the effects of FM-3422, and possible metabolites. It was agreed that this suggestion should be given further consideration.

R.A. Nelson stated that I.R.D.C. is now saving monkeys for the two year animal studies. If we are to use these animals, we must purchase them now at a cost of \$61,280 and pay \$7800 per month to maintain them. I.R.D.C. wants an answer by May 1, 1978. If we do not purchase and maintain these monkeys, none may be available later for the animal studies. However, since it has not yet been decided with certainty that monkeys will be used in the two year studies, those present recommended not purchasing the monkeys at this time.

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Those present again considered the available toxicity data on FC-95, FM-3422 and FC-143. It was pointed out that male rats fed FC-143 at the 1000 ppm level had about 50 ppm FC-143 in their blood and that one Chemlite worker had a level of 53 ppm in his blood. At the 1000 ppm feeding level, male rats had liver discoloration (females had none). It was concluded that the liver discoloration in rats associated with a blood level of 50 ppm suggests a possible human health problem for individuals who have this level (or above) in their blood for long periods of time. Those present also concluded the following:

As concluded previously by the full committee, available data in man indicates that no substantial risk exists under the Toxic Substances Control Act. However, those present urgently recommended that all reasonable steps be taken immediately to reduce exposure of employees to these compounds.

It was also agreed that:

1. R. E. Ober will make proposals on metabolic studies and make a presentation to the committee on such studies.
2. R. A. Prokop and J. E. Long will make certain that Riker has all previous analytical and toxicological data involving fluorochemicals in blood.
3. A protocol should be written for sampling of employees blood.
4. It will be necessary to have a method for analyzing FC-95, FM-3422 and FC-143 in the food used in animal studies.

Submitted by:


R. A. Prokop

RAP:df

attachment

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