

ASSIGNMENT OUTLINE & REPORT

ASSIGNEE

W. A. Knapp

ASSIGNMENT NO.

817

SHEET

1 of 2

A - OUTLINE		INTRA-CO. ASSIGNMENT		OUTSIDE ASSIGNMENT	
LOCATION	DEPARTMENT	NAME OF COMPANY	LOCATION		
		Food & Drug Admin.	Washington, D. C.		
CONTACT MR.	TITLE	CONTACT MR.	TITLE		
		Dr. A. J. Lehman	Chief, Dept. of Pharmacology		

ASSIGNMENT:

Vinyl Chloride - Propellant 1140

PERIOD OF ANTICIPATED ABSENCE	SIGNATURE	TITLE	DATE
FROM: 12-15 1958	Original Signed J. W. Swaine		
TO: 12-15 1958		Technical Director	12-17-58

B - REPORT

FROM:

IS

TO:

IS

Call was made to review our proposal on vapor inhalation toxicity of vinyl chloride. Present were Drs. Lehman, Nelson and Draize for Food and Drug; Drs. Greenberg and Lester of Yale University; our toxicologists, Mr. P. J. Cambourellis of Solvay Process Division for whom work is to be done, and the writer. Mr. Ramsey of FDA was present momentarily, but excused himself when it was determined that we did not contemplate the use of vinyl chloride as a propellant in food products.

Dr. Draize thought the program completely satisfactory, but when Dr. Lehman mentioned complete pathology (some 24-26 tissues) on at least a couple of animals, Dr. Nelson was called in for his opinion. Dr. Nelson wants complete pathology on at least six animals (3 males and three females) and would like an exposure concentration which shows some deleterious effects. As a counter to the latter proposal, Dr. Greenberg explained our proposal to determine highest concentration not producing symptoms on acute exposure to man and testing this concentration sub-acutely on rats (1-2 weeks; 8 hrs. daily exposure). This preliminary animal screening may or may not produce any pathology in the animals but Dr. Greenberg explained that it seemed rather ridiculous to expose at a higher concentration than produces symptoms on single short exposures in man. It must be recognized that if toxic effects (sub-normal weight gains, etc.) appear during this preliminary test exposure period we will probably have to do complete pathology on a few animals at this point which may increase histopathology expense somewhat. However, if this occurs we will probably not have to examine as many tissues at the conclusion of the long term (3 mos.) test. In any case, all tissues will be preserved in formalin for future section and examination if necessary. It is not expected that revisions in program will appreciably alter total expense.

1. Summary report of work and results
2. Cover by separate letters, recommendations and suggestions - make reference to letters in "Report" section above
If report detailed in Research Triplicating Book give Book and page nos.
4. Where log is prepared reference is also suggested

SIGNATURE	Original Signed W. A. Knapp	DATE	DEC 23 1958
	Research Consultant	Original Signed J. W. Swaine	DEC 23 1958
	Technical Director		

ASI 000015791

Other aspects of the program were favorably commented upon. Dr. Lehman likes preliminary human tests and was pleased with the transaminase[^] proposed as an indication of tissue damage.

On the question of inhibitor, Dr. Lehman could visualize no effect arising from 50-100 ppm of phenol in the vinyl chloride and the writer still feels that maximum protection for the investment is obtained if inhibitor is included; Solvay can counter this opinion if they desire.

On gas needed, based on 2.5% gas, three complete changes of atmosphere per hour, 8 hr. exposure, 5 days per week for 15 weeks using Yale's 1200 l. chamber we need about 332 lbs. of gas. To allow for waste and other factors, the writer suggests that 600 lbs. of gas be shipped to Yale. This should preferably all be from the same storage and all cylinders should contain the same amount of inhibitor.

We anticipate that experimental work should be underway within the first two weeks of January.

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WAK:nem

cc: Solvay Process Div., Mr. P. J. Cambourelis
N.Y.O.

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24AR

December 5, 1958

Dr. Leon Greenberg
Yale University
Laboratory of Applied Biodynamics
52 Hillhouse Avenue
New Haven, Connecticut

Dear Leon:

Appointment with Dr. A. J. Lehman is set for 9:00 A.M. on Monday, December 15th. If you and Dave are taking the night train, I suggest that we meet in the Washington Station between 7 and 8 A.M.

I will probably also take the night train which I think must be vacated at 7 or 7:30 A.M., so will probably see you at breakfast there.

If we miss, Dr. Lehman's office is in the South Agricultural Building, corner of 12th and C Sts. Telephone number is REpublic 7-4142, Extension 4708.

See you on the 15th -

Very truly yours,

Original Signed
W. A. Knapp

W. A. Knapp
Research Consultant

WAK:nem

ASI 000015793

December 3, 1958

Mr. P. J. Cambourelis
SOLVAY PROCESS DIVISION
Allied Chemical Corporation
40 Rector Street
New York 6, New York

Dear Mr. Cambourelis:

Attached herewith is proposed program of study which we intend to send to Dr. Lehman shortly before our proposed conference with him. The program is essentially that proposed by Yale University with minor revisions by the writer.

It is our plan to request (via telephone) an appointment for the week of December 15th.

May we have your approval on program as outlined.

Very truly yours,

Original Signed
W. A. Knapp
W. A. Knapp
Research Consultant

WAK:nem
enc. 1

cc: Dr. Leon Greenberg
Yale University
Laboratory of Applied Biodynamics
Yale Station
52 Hillhouse Avenue
New Haven, Connecticut

ASI 000015794