

APR 7 1976



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

April 1, 1976

Mr. Albert C. Clark
Manufacturing Chemists Assn.
1825 Connecticut Avenue, N.W.
Washington, DC 20009

Dear Mr. Clark:

This is to acknowledge receipt of your letter of March 23, 1976, transmitting the final report entitled, "The Effects of Maternally Inhaled Vinyl Chloride on Embryonal and Fetal Development in Mice, Rats and Rabbits."

This information will be considered in our evaluation of the use of vinyl chloride polymers in contact with food. Accordingly, as you are aware, it may be necessary to place this report on public display at the Hearing Clerk when final regulations are published.

We have not been conducting any animal studies on the potential toxicity of FD&C Red No. 2. We have been analyzing various samples of PVC coatings, gasket material, plasticized film, and flexible tubing. To date, we have been unable to detect any migration of vinyl chloride from these types of articles at a level of sensitivity of 1 part per billion. We are looking forward to the receipt of further reports of the studies being sponsored by MCA.

Sincerely yours,

Gerard L. McCowin
Assistant to the Director
Division of Food and
Color Additives, HFF-334

ASI 00022238

Name of substance Synonyms ¹	Species (Strain)	Exposure	Stage of experiment	Principal investigators
5. <u>Furfural</u> (CAS Reg. No.: 98-01-1; 2-Furaldehyde; 2-Furancarboxal; α-Furole)	Hamster (Syrian Golden)	inhalation	histology in progress	Feron, V.J. & Kruysse, A.
6. <u>Iron oxide</u> (CAS Reg. No.: 1309-37-1; Ferric oxide; C.I. 77491; Ferric sesquioxide; Jeweler's rouge; Hematite)	Hamster (Syrian Golden)	i.tr. alone & in combination with Diethyl- nitrosamine (inhal. & i.tr.)	completed published ¹	Feron, V.J.
7. <u>γ-Irradiated chicken</u>	Rat (Wistar)	p.o. in the diet	completed to be published	Til, H.P.
8. <u>Methylbenzocyanate</u>	Rat (Wistar)	p.o. in the diet	in progress	Til, H.P.
9. <u>3-Methylthio-2-butanone-O-[(Methylamino)carbonyl]oxime</u>	Rat (Wistar)	p.o. in the diet	in progress	Til, H.P.
10. <u>N-Nitrosodiethylamine</u> (CAS Reg. No.: 55-18-5; Diethylnitrosamine; DEN; DENA)	Hamster (Syrian Golden)	i.t.	completed published ¹	Feron, V.J.
11. <u>Vinyl chloride</u> (CAS Reg. No.: 75-01-4; Chloroethene; Chloethylene; Chloroethene; Chloroethylene; Ethylene monochloride; VC; VCM)	Rat (Wistar)	p.o. in the diet & inhal.	in progress	Feron, V.J. Til, H.P. & Kruysse, A.
12. <u>Yeast (grown on gas-oil)</u>	Rat Mouse	p.o. -d i t t o-	completed -d i t t o-	Feron, V.J.
13. <u>Yeast (grown on pure n-paraffins)</u>	Rat (Wistar) Mouse	p.o. -d i t t o-	completed -d i t t o-	Feron, V.J.

ASI 00022239

¹ See Appendix I

ASI 00022240

Name of substance (Synonyms)	Species (Strain)	Exposure	Stage of experiment	Principal investigators
10. <u>Span 60</u> (CAS Reg. No.: 1338-41-6; Sorbitan monostearate)	Mouse (TFI)	p.o. in the diet	histopatho- logical exami- nation to be carried out	BIBRA staff
11. <u>Stearoyl lactic acid, sodium & calcium salt</u>	Rat		planned	
12. <u>Tartrazine</u> (CAS Reg. No.: 1934-21-0; C.I. Acid Yellow 23, trisodium salt; 5-Hydroxy-1-(p-sulpho- phenyl)-4-[(p-sulphophenyl)- azolpyrazole-3-carboxylic acid, trisodium salt; C.I. 19140; C.I. Food yellow 4; FD & C yellow 5; Tartar yellow N)	Mouse (CSI)	p.o. in the diet	completed to be published ¹	BIBRA staff
13. <u>γ-Undecalactone</u> (CAS Reg. No.: 104-67-6)	Mouse		discontinued	
14. <u>Vinyl chloride</u> (CAS Reg. No.: 75-01-4; Chlorethene; Chlorethylene; Chloroethene; Chloroethylene; Ethylene monochloride; VC; VCM)	Rat (Wistar)	p.o. in drinking water	in progress	BIBRA staff

Chemical	Principal Investigator	Name of Department/Laboratory & Address
10. <u>Testosterone & dihydrotestosterone</u>	Habibi, F.K.	Division of Steroid Endocrinology, 26-28 Hyde Terrace, Leeds LS2 9LN, UK
20. <u>Titanium dioxide</u> (CAS Reg. No.: 13463-67-7; Titanium oxide; Ilmenite; Rutiox cr; Titania; Unitane)	Selikoff, I.J.	Environmental Sciences Laboratory, Mount Sinai School of Medicine, The City University of New York, 100th Street & 5th Avenue, New York, N.Y. 10029, USA
21. <u>Trichloroethylene</u> (CAS Reg. No.: 79-01-6; 1- Chloro-2,2-dichloroethylene; Ethinyl trichloride; Tri- chloroethene; Algylen; Germalgene; Trichloran; Tri- clene; Westrosol)	Axelson, O.	Department of Occupational Medicine, Regional Hospital, S-70185 Orebro, Sweden
22. <u>Vinyl chloride</u> (CAS Reg. No.: 75-01-4; Chlor- ethene; Chlorethylene; Chloro- ethene; Chloroethylene; Ethylene monochloride; VC; VCM)	Thiess, A.M.	Medical Department, Badische Anilin- und Sodafabrik, BASF-AG, Brunchstrasse, Ludwigshafen, Federal Republic of Germany
	Bartalini, E.	Medicina e Igiene del Lavoro, Montedison & Consociate, Via A. Appiani, 12, 201212 Milan Italy
	Duncan, K.D.	Employment Medical Advisory Service, Health & Safety Executive, Baynard's House, Chepstow Place, London W2, UK
	Selikoff, I.J.	Environmental Sciences Laboratory, Mount Sinai School of Medicine, The City University of New York, 100th Street & 5th Avenue, New York N.Y. 10029, USA

lix II
vi

Chemical	Principal Investigator	Name of Department/Laboratory & Address
22. <u>Cont'd</u>	Bertazzi, P.A.	Clinica del Lavoro "L.Devoto", Università degli Studi, via S. Barnaba 8, Milan, Italy
23. <u>Vinyl chloride polymers</u> (CAS Reg. No.: PM9002-86-2; Chloroethylene polymer; Poly- vinyl chloride; Blacar; Opalon; Vynon)	Bertazzi, P.A.	Clinica del Lavoro "L. Devoto", Università degli Studi, via S. Barnaba 8, Milan, Italy
	Ottevanger, C.F.	Department of Industrial Health, Shell Co., P.O. Box 7000, Rotterdam, The Netherlands
	Duncan, K.D.	Employment Medical Advisory Service, Health & Safety Executive, Baynard's House, Chepstow Place, London W2, UK
24. <u>Vinylidene chloride</u> (CAS Reg. No.: 75-35-4; 1,1- Dichloroethylene; asym- Dichloroethylene)	Pell, S.	Medical Division, E.I. du Pont de Nemours & Co. 11400 Nemours Building, Wilmington, Delaware 19898, USA