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KETTERING LABORATORY OF APPLIED PHYSIOLOGY

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June 14, 1950

Mr. Wm. E. McCormick
B.F. Goodrich Company
Dept. of Industrial Hygiene
and Toxicology
Akron, Ohio

Dear Mac:

Enclosed find two copies of our report
on VL-600 Resin.

Sincerely yours,


Joseph F. Treon

JFT:RT
encl.

Copy of report sent to Alexander at B.F.G. Chem. Co. 6/15/50
Leon 652

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The Immediate Toxicity of VL-600 Resin

Scope

The purpose of this investigation was to determine the immediate toxicity of a resin VL-600 when given orally to rabbits, dogs and a monkey.

Conclusions

1. All animals survived without any untoward reactions when given a single oral dose of VL-600 resin. The highest dosages given to rabbits, dogs and a monkey were, respectively, 23.7 g./kg., 20.3 g./kg. and 5.95 g./kg.
2. A rabbit survived without any untoward reactions following the oral administration of 5 g. of the resin per kg. of body weight on each of 5 successive days.
3. A dog survived without any ill effects after having been given 2.3 g. of the resin per kg. of body weight on each of 6 successive days.
4. When given in large doses, this material appears to be poorly absorbed and innocuous.

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5. Postmortem examinations of the animals after administration of the resin orally, in single or repeated doses, revealed only minor and apparently irrelevant abnormalities in a few instances.

Material Employed

VL-600 Resin is a copolymer of vinyl chloride and vinylidene chloride. It is insoluble in water. The material employed was a hard, gritty "off-white" powder which was supplied as "spray dried VL-600 Latex," by the Avon Lake Experimental Station of the B.F. Goodrich Chemical Company.

Experimental Methods

Oral Administration to Rabbits. Because of the insolubility and grittiness of the material, even after being ground in a mortar, a weighed amount of the resin was placed in a large hypodermic syringe and shaken well with 1 per cent aqueous solution of methocel. The syringe was attached to a large catheter (F16 or F22) passed through the esophagus of the rabbit. Additional methocel was added to the syringe to wash all of the material into the stomach.

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When 5.0 g. of the resin per kg. was given repetitively in 1 per cent methocel to a rabbit, an average of 23.5 ml. of suspension per kg. was given each day (range 21.8 to 24.7 ml. of suspension per kg.).

Oral Administration to Dogs. The undiluted material was given to dogs in size 000 gelatin capsules by way of the esophagus, whether the material was given on one occasion or on several successive days.

Oral Administration to a Monkey. By similar means the undiluted material was given to a monkey in 28 size 0 gelatin capsules.

Experimental Results

Oral Administration of a Single Dose. The data presented in Table 1 show that 5 rabbits survived when dosages from 7.1 to 23.7 g. per kg. were given as a suspension in aqueous methocel. No significant alteration occurred in their weights (cf. Table 1), and no signs of intoxication were apparent. The fecal matter contained considerable gritty material indicating that much of the material was unabsorbed.

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Two dogs, given, respectively, 18.4 and 20.3 g. of VL-600 resin per kg. (19 and 26 capsules, respectively), survived without any untoward reactions or significant alterations in weight (cf. Table 1).

A monkey survived without ill effects when given 5.95 g. per kg. (cf. Table 1). Nineteen and one-half hours after the dose had been given, objects that appeared to be the contents of 7 capsules were observed in the fecal matter, the gelatin container having been dissolved away leaving the contents apparently intact in their original shape. Two and three days, respectively, after the dose had been given, the contents of 8.5 and 6.5 capsules were found in similar condition in the feces. Thus 22 of the 28 capsules were evacuated without any obvious evidence of absorption.

Postmortem examinations, including histologic study of the tissues, revealed no lesions in these animals which appeared to have resulted from the administration of the resin. Certain abnormalities were present in occasional animals, and were regarded as evidences of unrelated spontaneous disease; thus,

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two rabbits (F304, F328) had slight evidences of degenerative changes in the myocardium, and one of these two (F328) also had slight parenchymatous degeneration of the renal convoluted tubules. In addition, the monkey had moderate fatty infiltration of the central zones of the liver lobules, and there was a single cyst (parasitic) of the liver.

Repetitive Oral Administration. A rabbit showed no ill effects and survived following the oral administration of 5.0 grams of resin per kg. of body weight on each of 5 successive days (given in suspension in aqueous methocel (cf. Table 2). A rough inspection of the fecal matter revealed the presence of gritty material in amounts which did not appear to be equivalent to those administered.

A dog survived when given 2.3 grams of the resin per kg. (5 capsules each day) on each of 6 successive days. Ten minutes after the administration of the first dose, 2 of the capsules were regurgitated. Twenty-one hours after the administration of the 3rd dose (which consisted of 25.9 g. of resin) 13.8 g. of the undissolved gritty particles, assumed to be

the resin, were found in the feces. The day following the administration of the 4th dose (25.5 g. of resin) 21.9 g. of similar material were found in the feces.

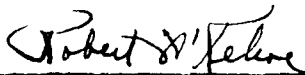
There were no lesions in the viscera of the dog. The rabbit was found at autopsy to have coccidiosis of the liver, and microscopically there was moderate interstitial myocarditis.

From the Kettering Laboratory in the Department of Preventive Medicine and Industrial Health, College of Medicine, University of Cincinnati, Cincinnati, Ohio.

Report and Experimental Work By:

Joseph F. Treon, Ph.D.
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Approved


Robert A. Kehoe, M.D.,
Director

Date June 13, 1950

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Table 1

The Immediate Toxicity of VL-600 Resin When Administered Orally in a Single Dose to Rabbits, Dogs and a Monkey

Identification Number	Dose		Initial Weight kg.	Loss of Weight Expressed as Percentage of Initial weight	Fate	Length of Survival
	g. of VL-600 Resin /kg.	Total Ml. 1% Me-cel Added				
Rabbits						
F306	23.7	130.0	3.195	- 1.7	Survived	7 days; killed
F345	16.0	80.0	2.397	- 0.8	Survived	8 days; killed
F344	15.1	75.0	2.647	0	Survived	8 days; killed
F304	10.7	70.0	3.552	- 2.6	Survived	11 days;killed
F328	7.1	40.0	2.065	- 0.4	Survived	7 days; killed
Dogs						
A46	20.3	(1)	7.430	- 2.2	Survived	7 days; killed
A44	18.4	(1)	5.940	- 3.0	Survived	8 days; killed
Monkey						
M85	5.95	(1)	4.306	- 2.3	Survived	7 days; killed

(1) Given undiluted in capsules.

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Table 2

The Effects of the Oral Administration of Multiple Doses of a Suspension of
VL-600 Resin in 1 Per Cent Methocel to a Rabbit and of Undiluted Resin in
Capsules to a Dog

Identifi- cation Number	Number of Doses	Daily Dose		Initial Weight kg.	Change in Weight Expressed as Percentage of Initial Weight		Fate	Length of Survival
		Ml. of Suspension Average	g. of VL- 600/kg.		During Period of Applica- tion	After Period of Applica- tion		
Rabbit F431	5	50.2	5.0	2.204	- 2.0	+ 9.1	Survived	Killed 3 days after 5th dose
Dog A36	6	- -	2.3	11.115	- 0.5	- 0.7	Survived	Killed 3 days after 6th dose

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FEDERAL SECURITY AGENCY
FOOD AND DRUG ADMINISTRATION
WASHINGTON 25, D. C.

JUN 15 1950

Dr. William E. McCormick
Dept. of Industrial Hygiene and Toxicology
The B. F. Goodrich Company
Akron, Ohio

Dear Dr. McCormick:

Your letter of June 6 requests a written confirmation of the views expressed at the June 5 meeting.

Your reports covering the toxicity studies on Geon 202 Resin, Acetyl Tributyl Citrate, and Santicizer B-16, as well as the extraction studies on the finished film using typical food-type solvents indicate to us that there is little chance of any danger resulting from the use of such film for wrapping food.

As you know, the responsibility for determining that a food does not become adulterated by being wrapped in a container which may render it dangerous to health is that of the manufacturer or shipper and cannot be shared by this Administration.

Very truly yours,

Bert J. Vos, M.D.

Bert J. Vos, M.D.
Acting Chief, Division of Pharmacology

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News about

B. F. Goodrich
Chemical Company
raw materials

TECHNICAL HELP **for manufacturers of** **vinyl-coated fabrics**

GOVERNMENT requirements are now increasing for products in which vinyl-coated fabrics are required.

For instance, Geon polyvinyl paste resin coated onto cloth resists the action of hazardous chemicals—an important safety factor. Fabrics treated with Geon latex compound help protect the wearer against fire. Garments so treated can be washed or cleaned in any type soap or detergent and still retain their protective qualities. The garments are also mildew-proof and, of course, non-toxic and are comfortable to wear.

The protective qualities of vinyl-treated fabrics are required in many Military and Navy specifications. Fabric coaters who want technical help on processes for making these protective fabrics should write to Dept. GH-21, B. F. Goodrich Chemical Company, Rose Building, Cleveland 15, Ohio. Cable address: Goodchemco.



GEON RESINS • GOOD-RITE PLASTICIZERS
...the ideal team to make products easier,
better and more saleable.

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Proof from The Griswold-Eshleman Co., Cleveland
Daily News Record—October 4, 1950 (GH-21)

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