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Via Federal Express

Attn: TSCA Declassification Coordinator  
U.S. Environmental Protection Agency  
Office of Pollution Prevention and Toxics  
Confidential Business Information Center (CBIC)  
EPA East Building, Room 6428  
1201 Constitution Avenue  
Washington, D.C. 20004

Public Copy

Subject: Declassification Activity – TSCA §8(e) Supplement  
DCN: 8EHQ-92-13178 (88920010981)

Dear TSCA Declassification Coordinator:

Please find enclosed a revised public copy of the above-identified submission. Some of the information claimed as confidential is released in the attached document. The document control number has been noted on the attached document.

Please note that withdrawal of confidentiality is limited to specific information in the above-identified submission only. No property rights in the study in question are being relinquished.

Very truly yours,



**Company Sanitized**

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Materials Tested

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- 1)
- 2) Ethane, 1,1,1-trichloro-, mixed with 1,1,2-trichloro-1,2,2-trifluoro-ethane and 4-methyl-2-pentanone

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INHALATION APPROXIMATE LETHAL CONCENTRATION (ALC)  
OF USE SOLUTION WITH SOLVENT CONTROL

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**SUMMARY:** Groups of 6 male Cr1:CD® rats were exposed for single, 4-hour periods to atmospheres of either Use Solution (a system of particulate suspended in solvent) or the Solvent Mix for Use Solution. An ALC for Teflon® SBA Use Solution is 72 mg/m<sup>3</sup> of particulate combined with 36,000 mg/m<sup>3</sup> of solvent. An ALC for the Solvent Mix alone is 64,000 mg/m<sup>3</sup>.

Based on total atmospheric concentration (particulate and solvent), Use Solution is considered slightly toxic by inhalation. The particulate portion of Use Solution contains 41% by weight, which is known to be extremely toxic by inhalation (ALC is 42 mg/m<sup>3</sup>). The estimated concentration in the Use Solution ALC is 29 mg/m<sup>3</sup>. Therefore, both and the Solvent Mix were present in near-lethal concentrations in the Use Solution ALC. Hence, the deaths cannot clearly be attributed to the presence of .

- I. **INTRODUCTION:** The purpose of this study was to determine an ALC for Use Solution. Use Solution contains 0.31% by weight Telomer B citrate urethane<sub>3</sub>(TBCU). is extremely toxic by inhalation (4-hour ALC is 42 mg/m<sup>3</sup>; HL-423-83). Therefore, a solvent control was tested to determine whether contributes significantly to Use Solution's toxicity.

- II. **PROCEDURES:**

- A. **Animal Husbandry:** Young adult male Cr1:CD® rats were received from Charles River Breeding Laboratories, Kingston, New York.

II. PROCEDURES: (cont'd)

Rats were housed singly in 5"x11"x7" stainless steel, wire-mesh cages in rooms maintained at 50 + 10% relative humidity and 74 + 2°F on a 12/12 hour light/dark cycle. Each rat was assigned a unique, 6-digit identification number which corresponded to a numbered card on the outside of its cage. Except during exposures, Purina Certified Rodent Chow® #5002 and water were available ad libitum. Rats were quarantined for 1 week prior to testing. Rats were weighed and observed twice during the quarantine period.

B. Exposure Protocol: Groups of 6 rats, 7-8 weeks old and weighing between 235-262 grams, were restrained in perforated, stainless steel cylinders. Each group was exposed nose-only for a single, 4-hour period to either Use Solution or the Solvent Mix for Use Solution. All surviving rats were weighed and observed daily for 14 days post exposure, weekends included when deemed necessary.

C. Test Material:

1) Use Solution

Composition: Active Ingredient:  
fluoromonomer  
2-Ethylhexyl methacrylate  
Methylolacrylamide  
Hydroxyethyl methacrylate  
Telomer B citrate urethane  
Methyl isobutyl ketone  
Methylchloroform  
1,1,2-Trichloro-1,2,2-trifluoroethane

Other Codes:

Synonyms: Use Solution

Submitted by:

2) Solvent Mix for Solution

Composition: Methyl isobutyl ketone  
Methylchloroform  
: 1,1,2-trichloro-1,2,2-tri-  
fluoroethane

Synonyms: ● Solvent mix for Use Solution  
● Solvent mix for

Submitted by:

## II. PROCEDURES: (cont'd)

- D. Atmospheric Generation: Liquid test material was pumped into a Spraying Systems® nebulizer. Air introduced at the nebulizer aerosolized/evaporated the test material and swept the aerosol/vapor stream into a cyclone. The cyclone is designed to remove large particles by inertial impaction, while aerodynamic particles pass through the cyclone and into the exposure chamber. For Solvent Mix exposures, the evaporated solvent simply passed through the cyclone.
- E. Analytical: Two different analytical methods were used in these tests. For both materials, a gas chromatographic method was used to monitor solvent concentration. For Use Solution, a gravimetric method was used to monitor particulate concentration.
1. Gas Chromatographic Method: Samples of chamber atmosphere were collected at 30-45 minute intervals with a gas-tight syringe. Samples were analyzed for total solvent concentration with a Hewlett-Packard 5710A Gas Chromatograph equipped with a flame ionization detector. Samples were chromatographed isothermally at 90°C on a 6 ft. x 4 mm I.D. glass column packed with 10% SE-30 on 60/80 mesh Chromosorb® W. For two exposures, G.C. oven temperature was increased to 135°C. Concentrations were determined by comparing detector response with standard curves. Standards were prepared by quantitatively evaporating liquid Solvent Mix for Teflon® SBA Use Solution in calibrated gas bottles.
  2. Gravimetric Method: At 15-30 minute intervals, calibrated volumes of chamber atmosphere were drawn through pre-weighed, glass-fiber filters. Filters were weighed on a Cahn 26 Automatic Electrobalance®. Atmospheric concentration of particulate was determined by the filter weight differential before and after sampling.

Chamber temperatures were monitored with thermometers. Relative humidity was measured once with a Bendix® Model 556 Psychrometer. For Use Solution exposures, particle size (mass median diameter) and percent of respirable particulate were determined with a Sierra Cascade Impactor.

## III. RESULTS:

### A. Teflon® SBA Use Solution:

1. Data: A slight cloud was visible in a beam of light during all exposures. Chamber temperature ranged between 24-25°C, and relative humidity was 30%.

III. RESULTS: (cont'd)

For these exposures, generation conditions were varied based on particulate concentration. During some exposures, large changes in air flows were needed to maintain a steady particulate concentration, causing large fluctuations in the corresponding solvent concentration. Further, the ratio of solids to solvent was not consistent between exposures because, at a given liquid flow, higher air flows increase the efficiency of particulate generation, but dilute the corresponding solvent concentration.

Table I  
Use Solution - Atmospheric Characterization and Mortality

Exposure No.	Particulate <sup>1</sup> Concentration (mg/m <sup>3</sup> )			Solvent <sup>2</sup> Concentration (mg/m <sup>3</sup> )			Mortality (#deaths/ # exposed)
	Mean	S.D.	Range	Mean	S.D.	Range	
1	64	10	41-73	44,000	18,000	32,000-85,000	0/6
2	72	5.3	64-82	36,000	3,000	30,000-40,000	5/6
3	82	13	56-100	32,000	2,400	28,000-35,000	7/6
4	91	22	64-140	60,000	3,000	43,000-97,000	6/6

Exposure No.	% Respirable <sup>3</sup>	Mass Median Diameter of Respirable Particulate <sup>4</sup>
1	-	-
2	94	1.4 um
3	94	1.1 um
4	94	1.4 um

<sup>1</sup> Combined TBCU and active ingredient concentrations.

<sup>2</sup> Combined Freon® 113, methylchloroform and methyl isobutyl ketone concentrations.

<sup>3</sup> % by weight of particles with aerodynamic diameter less than 10 um.

<sup>4</sup> Calculated for respirable fraction of atmosphere only.

2. Observations: During exposures, all rats had labored breathing. At particulate concentrations greater than 64 mg/m<sup>3</sup>, rats had reduced response to sound and to a tail pinch.

During the post-exposure period, rats exposed to 64 mg/m<sup>3</sup> particulate and the surviving rat exposed to 72 mg/m<sup>3</sup> particulate had slight to moderate weight loss for 1 day post

III. RESULTS: (cont'd)

exposure, followed by normal weight gain. No adverse clinical signs were observed in these rats. At 72 mg/m<sup>3</sup>, deaths occurred overnight. At 82 mg/m<sup>3</sup>, rats died between 1 and 3 days post exposure. Clinical signs at this concentration included weight loss, labored breathing, lung noise, lethargy, wet perineum, pallor, tremors, ruffled fur, hunched posture and red nasal discharge. At 91 mg/m<sup>3</sup>, rats died either during exposure or overnight.

B. Solvent Mix for Use Solution

1. Data: Chamber temperatures ranged between 25-27°C.

Table II

<u>Solvent Mix for</u>		<u>Use Solution - Atmospheric Concentrations</u>		<u>Mortality</u> (# deaths/# exposed)
<u>Mean</u>	<u>Concentration (mg/m<sup>3</sup>)<sup>1</sup></u> <u>S.D.</u>	<u>Range</u>		
37,000	14,000	31,000 - 74,000		0/6
45,000	3,600	36,000 - 48,000		0/6
64,000	14,000	42,000 - 83,000		1/6
85,000	3,700	79,000 - 89,000		0/6
100,000	3,700	91,000 - 100,000		5/6
140,000	12,000	130,000 - 150,000		6/6

<sup>1</sup> Combined Freon® 113, methylchloroform and methyl isobutyl ketone concentrations.

2. Observations: During exposures, rats exposed to concentrations greater than 45,000 mg/m<sup>3</sup> had no response to a tail pinch and/or to sound. At 100,000 mg/m<sup>3</sup>, 5/6 rats died during exposure. At 140,000 mg/m<sup>3</sup>, all rats died within 1 hour of exposure.

When released from restrainers, all surviving rats were lethargic. At 85,000 mg/m<sup>3</sup>, rats were limp and had labored breathing. The surviving rat at 100,000 mg/m<sup>3</sup> was barely breathing.

During the post-exposure period, surviving rats exhibited slight weight loss for 1 day post exposure, followed by normal weight gain. At 64,000 mg/m<sup>3</sup>, 1 rat was found dead the morning after exposure. Except for 1 rat exposed to 64,000 mg/m<sup>3</sup> which had labored breathing and a partially closed eye 1

III. RESULTS: (cont'd)

day post exposure, no adverse clinical signs were seen during the recovery period.

- IV. CONCLUSION: An ALC for Use Solution is  $72 \text{ mg/m}^3$  of particulate combined with  $36,000 \text{ mg/m}^3$  of Solvent Mix. An ALC for the Solvent Mix alone is  $64,000 \text{ mg/m}^3$ . Based on total atmospheric concentration (particulate and solvent), Use Solution is considered to be slightly toxic by inhalation. The Solvent Mix is considered to have very low toxicity by inhalation.

Both TBCU and the Solvent Mix were present in near-lethal concentrations in the ALC. For comparison purposes, the previously determined ALC for is  $42 \text{ mg/m}^3$ , and the estimated TBCU concentration in the Use Solution ALC is  $29 \text{ mg/m}^3$ . Therefore, the deaths cannot be attributed to the presence of TBCU.

Work and Report by:

Supervised by:

Study Director:

Approved by:

Date Issued: June 18, 1984  
Study Initiated/Completed: 9/6/83-9/29/83

Number of pages in this report: 6