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8ECP

Submitting Organization

UNION CARBIDE CORP

Contractor

BUSHY RUN RES CTR

Document Title

INITIAL SUBMISSION: METHYL CELLOSOLVE ACETATE: ACUTE TOXICITY & PRIMARY IRRITANCY STUDIES (PROJECT REPORT) WITH COVER SHEET & LETTER DATED C50492

Chemical Category

METHYL CELLOSOLVE ACETATE

8(e)

3682

# CAP

(COMPLIANCE AUDIT PROGRAM)

## TSCA CONFIDENTIAL BUSINESS INFORMATION

ORIGINAL - DCO (Jeff/Eric)  
COPY # 1 - CBIC  
COPY # 2 - Scott Sherlock

## COMPANY SANITIZED

ORIGINAL - PINS  
COPY # 1 - PINS  
COPY # 2 - ECAD

## CONTAINS NO CBI

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UNION CARBIDE CORPORATION 39 OLD RIDGEBURY ROAD, DANBURY CT 06817-0001

May 4, 1992

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8EHQ-0592-43682 Init

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Office of Toxic Substances  
U.S. Environmental Protection Agency  
401 M Street, SW  
Washington, DC 20460



8892000237

Attn: Section 8(e) Coordinator (CAP Agreement)

Re: CAP Agreement Identification No. 8ECAP-0110

Dear Sir or Madam:

Union Carbide Corporation ("Union Carbide") herewith submits the following report pursuant to the terms of the TSCA §8(e) Compliance Audit Program and Union Carbide's CAP Agreement dated August 14, 1991 (8ECAP-0110). This report describes acute toxicity studies with methyl CELLOSOLVE® Acetate (CASRN 110-49-6).

"Methyl CELLOSOLVE® Acetate: Acute Toxicity and Primary Irritancy Studies", Bushy Run Research Center, Project Report 47-69, May 23, 1984.

A complete summary of this report is attached.

Previous TSCA Section 8(e) or "FYI" Submission(s) related to this substance are:

(None)

Previous PMN submissions related to this substance are: (None)

This information is submitted in light of EPA's current guidance. Union Carbide does not necessarily agree that this information reasonably supports the conclusion that the subject chemical presents a substantial risk of injury to health or the environment.

In the attached report the term "CONFIDENTIAL" may appear. This precautionary statement was for internal use at the time of issuance of the report. Confidentiality is hereby waived for purposes of the needs of the Agency in assessing health and safety information. The Agency is advised, however, that the publication rights to the contained information are the property of Union Carbide.

Yours truly,



William C. Kuryla, Ph.D.  
Associate Director  
Product Safety  
(203/794-5230)

WCK/cr

Attachment (3 copies of cover letter, summary, and report)

# SUMMARY

Project Report 47-69

## Methyl CELLOSOLVE Acetate

### Acute Toxicity and Primary Irritancy Studies

Sponsor: Union Carbide Corporation  
Ethylene Oxide Derivatives Division

\* \* \* \* \*

#### Summary

##### Peroral, Rat (Fasted)

Males: LD50 = 4.29 ml/kg; sample dosed as received.

Females: LD50 = 3.73 ml/kg; sample dosed as received.

##### Percutaneous, Rabbit

Males: LD50 = 4.49 ml/kg; sample dosed as received.

Females: LD50 = 3.36 ml/kg; sample dosed as received.

##### Inhalation, Rat; Substantially Saturated Vapor (Dynamic)

Males: 6 hours killed 0 of 5.

Females: 6 hours killed 0 of 5.

##### Skin Irritation, Rabbit (4-hr occluded)

No irritation on 6 rabbits from 0.5 ml.

##### Eye Irritation, Rabbit

Minor to moderate diffuse corneal injury (vascularization on one) in 6 of 6 eyes, moderate iritis in 6, moderate to severe conjunctival irritation in 6 from 0.1 ml; minor, transient, diffuse corneal injury in 2 of 6 eyes, moderate transient iritis in 5, minor to moderate conjunctival irritation in 6 from 0.01 ml; minor, transient, diffuse corneal injury in 5 of 6 eyes, moderate transient iritis in 2, moderate conjunctival irritation in 6 from 0.005 ml (healed within 3 days).



# BUSHY RUN RESEARCH CENTER

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Project Report 47-69  
16 Pages  
May 23, 1984

## Methyl CELLOSOLVE Acetate

### Acute Toxicity and Primary Irritancy Studies

Sponsor: Union Carbide Corporation  
Ethylene Oxide Derivatives Division

\*\*\*\*\*

#### Summary

##### Peroral, Rat (Fasted)

Males: LD50 = 4.29 ml/kg; sample dosed as received.  
Females: LD50 = 3.73 ml/kg; sample dosed as received.

##### Percutaneous, Rabbit

Males: LD50 = 4.49 ml/kg; sample dosed as received.  
Females: LD50 = 3.36 ml/kg; sample dosed as received.

##### Inhalation, Rat; Substantially Saturated Vapor (Dynamic)

Males: 6 hours killed 0 of 5.  
Females: 6 hours killed 0 of 5.

##### Skin Irritation, Rabbit (4-hr occluded)

No irritation on 6 rabbits from 0.5 ml.

##### Eye Irritation, Rabbit

Minor to moderate diffuse corneal injury (vascularization on one) in 6 of 6 eyes, moderate iritis in 6, moderate to severe conjunctival irritation in 6 from 0.1 ml; minor, transient, diffuse corneal injury in 2 of 6 eyes, moderate transient iritis in 5, minor to moderate conjunctival irritation in 6 from 0.01 ml; minor, transient, diffuse corneal injury in 5 of 6 eyes, moderate transient iritis in 2, moderate conjunctival irritation in 6 from 0.005 ml (healed within 3 days).

#### Interpretation

Methyl CELLOSOLVE Acetate was moderately toxic following its administration by single peroral intubation and single percutaneous application. Delayed times to death and weight loss in several rabbits indicated persistent toxic effect by the dermal route. Single inhalation exposure to dynamically

generated substantially saturated vapor for 6.0 hours did not kill any of the 5 male or 5 female rats tested. No signs of inhalation toxicity were observed. A 4-hour application to covered rabbit skin produced no irritation. Instillation of 0.1 ml of sample into rabbit eyes resulted in moderate, persistent injury. Volumes of 0.01 or 0.005 ml produced transient minor to moderate injury.

#### Sample

Quantity: 1 quart  
Submitted By: P. B. Stanley  
Date Received: December 21, 1983  
Division: Ethylene Oxide Derivatives  
Tarrytown, NY  
Identification: 131-413622-2;  
Ref. 271  
S-851837  
Charge No: 09200  
Description: Clear, non-viscous  
liquid.  
BRRC Sample No.: 46-352

Approximately 20 ml of the remaining sample will be retained for 2 years following issuance of this report.

#### Procedures

Descriptions of the test procedures are included in the attached standard test procedures section.

#### Results

Results of the peroral, percutaneous, inhalation and skin irritation tests are given in Tables 1 through 4, respectively. Eye test results are presented in Tables 5, 6 and 7, with a summary appearing in Table 8.

The peroral LD50 for male rats receiving Methyl CELLOSOLVE Acetate was 4.29 ml/kg; that for females was 3.73 ml/kg. Sluggishness, tremors, unsteady gait and labored breathing were among the signs of toxicity observed. Most deaths occurred at 6 min to one day. Survivors recovered at 2 to 4 days. In males, findings at necropsy included mottled and red lungs, liquid-filled stomachs, livers with tan patches, kidneys with tan patches, and 2 bladders with red liquid. Females exhibited no remarkable gross lesions.

By the percutaneous route, the LD50 was 4.49 ml/kg for males and 3.36 ml/kg for female rabbits. No skin reactions were noted. Signs of toxicity included sluggishness, unsteady gait, diarrhea and prostration. Deaths occurred at 2 to 14 days. The delayed times to death in victims and the consistent loss of weight among most survivors indicated persistent toxic effect from this route of administration. At necropsy, a few lungs and tracheas appeared mottled tan to red and there were a few intestines filled with soft fecal material.

Exposure to dynamically generated, substantially saturated vapor for 6.0 hours resulted in no deaths in male or female rats. There were no signs of inhalation toxicity observed and gross pathologic examination revealed no remarkable lesions.

A 4-hour application of 0.5 ml of sample to covered skin resulted in no erythema, edema or other irritation during the 3-day observation period.

A volume of 0.1 ml of sample instilled into rabbit eyes produced minor to moderate diffuse corneal injury in 6 of 6 rabbits, moderate iritis in 6 and moderate to severe conjunctival irritation in 6. After 3 days, most eyes had necrosis on the nictitating membrane. Three eyes were essentially normal after 7 days; 5 were healed at 14 days. Injury, including corneal vascularization, was evident in the sixth eye through 21 days. Instillation of 0.01 ml resulted in minor corneal injury in 2 of 6 eyes, moderate iritis in 5 and minor to moderate conjunctival irritation in all 6. Effects of the cornea and iris were no longer evident after 24 hours. Conjunctival irritation persisted in 5. Four eyes were normal at 48 hours and at 72 hours. After 7 days all eyes were healed. Similar results resulted from application of 0.005 ml. Five eyes had minor corneal injury, 2 had moderate iritis and all 6 had moderate conjunctival irritation. All corneal effects and most instances of iritis disappeared within 24 hours. Four eyes healed within 48 hours. All were normal after 72 hours.

Reviewed and Approved by:



Roy C. Myers, B.S.  
Study Director



Linval R. DePass, Ph.D.  
Manager, Oral/Dermal Toxicology

 5/23/84

Fred R. Frank, Ph.D.  
Director

Acknowledgements:

Single Peroral Tests

Susan M. Christopher, B.S.  
Master Technologist

Percutaneous, Skin and  
Eye Irritation tests

Tracy A. Monteleone, A.S., AALAS Cert. I  
Technologist

Inhalation Studies

David W. Falt, B.S., AALAS Cert. II  
Master Technologist

Table 1

Peroral Intubation, Single Dose to Rats

Material: Methyl CELLOSOLVE Acetate Sample No.: 46-352

Dosage, ml/kg	Dead/ Dosed	Days to Death	Weight Change, g		Signs of Toxicity	Gross Pathology
			7 Days	14 Days		
6.00	5/5	0,0,0,1,1	-	-	Sluggishness at 15 min; severe sluggishness in 2 at 10 min; death of 3 at 8 min to 2 hr.	Lungs mottled dark red and red; livers with tan patches on lobes adjacent to stomach; stomachs liquid-filled; bladder of 1 filled with dark red liquid; kidneys and spleens with tan patches on areas ad- jacent to stomach.
4.00	2/5	2, 5	36 to 48 (Mean=44)	95 to 109 (Mean=100)	Sluggishness at 3 hr; erratic tremors at 1 day; prostration and labored breathing in 1 at 1 day. Recovery of survivors at 2 to 4 days.	In victims, lungs red; liver of 1 with green patches on lobes adjacent to stomach; intestines green; bladder of 1 filled with dark red liquid. In survivors, lungs red.
2.00	0/5	-	59 to 91 (Mean=73)	114 to 164 (Mean=132)	None noted.	Nothing remarkable.

(Continued)

Table 1 (Continued)

Peroral Intubation, Single Dose to Rats

Material:	Methyl CELLULOSE Acetate	Sample No.:	Weight Change, g		Signs of Toxicity	Gross Pathology
			Days to Death	14 Days		
8.00	5/5	0,0,0,0,1	-	-	Sluggishness at 2 min; severe sluggishness at 5 min; unsteady gait, labored breathing at 6 min. Death of 4 at 6 min to 3 hr.	Nothing remarkable.
4.00	3/5	0,1,1	18 and 32 (Mean=25)	38 and 56 (Mean=47)	Death of 1 at 1 hr. Sluggishness at 2 hr; erratic tremors in 1 at 1 day. Recovery of 1 survivor at 2 days. Alopecia on facial area of 1 at 14 days.	Nothing remarkable.
2.00	0/5	-	25 to 45 (Mean=33)	28 to 64 (Mean=45)	None noted.	Nothing remarkable.

LD50's with 95% Confidence Limits:

Males: 4.29 (2.90 to 6.34) ml/kg; sample dosed as received.  
Females: 3.73 (2.52 to 5.52) ml/kg; sample dosed as received.

LD50 Slopes:

Males: 4.96  
Females: 4.96

Table 2

Percutaneous Application, Single Dose to Rabbits

Sample No.: 46-352

Material: Methyl CELLOSOLVE Acetate

Dose, ml/kg	Dead/ Dosed	Days to Death	Weight change, g		Skin Irritation	Signs of Toxicity	Gross Pathology
			7 Days	14 Days			
8.00	3/5	2, 6, 8	-722 to -86 (Mean=-422)	-148 and 203 (Mean=28)	None noted.	Intermittent proctration in 1 at 1 day; diarrhea, emaciation in 1 at 7 days.	Nothing remarkable.
4.00	3/5	3, 4, 4	-591 and -250 (Mean=-420)	-259 and 151 (Mean=-54)	None noted.	None noted.	In victims, intes- tines with soft fecal material. In survivors, nothing remarkable.
2.00	0/5	-	-218 to -6 (Mean=-87)	-601 to 296 (Mean=-42)	None noted.	Emaciation in 1 at sacrifice.	Intestines of 2 filled with soft fecal material.

Male Rabbits

Table 2 (Continued)

Percutaneous Application, Single Dose to Rabbits

Material: Methyl CELLOSOLVE Acetate Sample No.: 46-352

Dosage, ml/kg	Dead/ Dosed	Days to Death	Weight change, g		Skin Irritation	Signs of Toxicity	Gross Pathology
			7 Days	14 Days			
8.00	5/5	2,4,4,4,6	-	-	None noted.	Sluggishness, unsteady gait to prostration at 1 day.	Lungs mottled tan to dark red.
4.00	3/5	7,12,14	-797 to -98 (Mean=-449)	-57 and 43 (Mean=-7)	None noted.	Sluggishness, unsteady gait in 1 at 1 day; diarrhea in 1 at 7 days.	In victims, intestines filled with soft fecal material. In survivors, lungs of 1 dark red.
2.00	1/5	8	-74 to 191 (Mean=25)	59 to 523 (Mean=254)	None noted.	Sluggishness in 1 at 7 days.	In victims, perinasal red encrustation. In survivors, nothing remarkable.

Female Rabbits

LD50's with 95% Confidence Limits:

Males: 4.49 (2.00 to 10.1) ml/kg; sample dosed as received.

Females: 3.36 (1.89 to 5.97) ml/kg; sample dosed as received.

LD50 slopes:

Males: calculation not possible.

Females: 3.48

WPC/fcz/01282-2  
04/24/84

Table 3

Inhalation of Substantially Saturated Vapor, Single Exposure to Rats; Dynamic Conditions at 23°C

Sample No.: 46-352

Material: Methyl CELLOSOLVE Acetate

Gross Pathology

Signs of Toxicity

Weight Change, g  
7 Days    14 Days

Days to Death

Duration

Dosed

Dead/

7 Days

14 Days

None noted.

(Mean=50)

69 to 108

(Mean=89)

None noted.

(Mean=26)

0/5

0/5

-

Male Rats

Nothing remarkable.

Female Rats

Nothing remarkable.

LT50's:

Males: 6.0 hours of exposure killed 0 of 5  
Females: 6.0 hours of exposure killed 0 of 5

WPC/fcz/0128Z-1  
04-17-84

Table 4

Primary Skin Irritation - Rabbit

Conditions: 0.5 ml dosed

Sample No.: 46-352

Material: Methyl CELLOSOLVE Acetate

Date: 01/16/84	Date: 01/16/84	Date: 01/16/84	Date: 01/16/84
Rabbit No.: 83-28454	Rabbit No.: 83-28467	Rabbit No.: 84-58	Rabbit No.: 84-63
Sex: Male	Sex: Male	Sex: Male	Sex: Female
			Rabbit No.: 84-54
			Sex: Female
			Rabbit No.: 84-71
			Sex: Female

Erythema & Eschar Formation

Time (After Initiation of Contact):	Score	Score	Score	Score	Score	Ave. Score
5 hours	0	0	0	0	0	0.0
1 day	0	0	0	0	0	0.0
2 days	0	0	0	0	0	0.0
3 days	0	0	0	0	0	0.0
7 days	-	-	-	-	-	-

Edema Formation

Time:	Score	Score	Score	Score	Score	Ave. Score
5 hours	0	0	0	0	0	0.0
1 day	0	0	0	0	0	0.0
2 days	0	0	0	0	0	0.0
3 days	0	0	0	0	0	0.0
7 days	-	-	-	-	-	-

Other Irritation or Effects

Time:	Effect	Effect	Effect	Effect	Effect
5 hours	-	-	-	-	-
1 day	-	-	-	-	-
2 days	-	-	-	-	-
3 days	-	-	-	-	-
7 days	-	-	-	-	-

Specific Effects/Remarks:

WPC/fcz/01282-2  
04-24-84

Table 5

Primary Eye Irritation-RabbitMaterial: Methyl CELLOSOLVE Acetate Sample No.: 46-352 Amount: 0.1 r

Rabbit No:	84-495	84-497	84-498	84-388	84-397	84-461	
Sex	Male	Male	Male	Female	Female	Female	
Date Dosed	02/28/84	02/28/84	02/28/84	02/28/84	02/28/84	02/28/84	
Scores/Effects at 1 hr							
Cornea: Opacity	0	1	1	1	1	1	Mean: 0.8
Area	0	1	2	2	2	1	1.1
Iris: Inflamm.	0	1	1	1	1	1	0.8
Conjunct: Redness	2	1	2	2	2	2	1.8
Chemosis	2	2	2	2	2	3	2.1
Discharge	3	3	3	3	3	3	3.0
Fluorescein Exam.	-	-	-	-	-	-	-
Other Effects/Remarks:							
Scores/Effects at 4 hr							
Cornea: Opacity	1	1	1	1	1	1	Mean: 1.0
Area	1	1	2	2	2	2	1.6
Iris: Inflamm.	1	1	1	1	1	1	1.0
Conjunct: Redness	2	2	2	2	2	3	2.2
Chemosis	3	3	3	3	3	4	3.0
Discharge	3	3	3	3	3	3	3.0
Fluorescein Exam.	-	-	-	-	-	-	-
Other Effects/Remarks:							
Scores/Effects at 24 hr							
Cornea: Opacity	0	0	1	1	1	1	Mean: 0.8
Area	0	0	2	4	2	2	1.6
Iris: Inflamm.	1	0	1	1	1	1	0.8
Conjunct: Redness	3	2	1	2	3	3	2.2
Chemosis	2	1	4	4	3	3	2.6
Discharge	3	1	3	3	3	3	2.6
Fluorescein Exam.	15%	0%	100%	95%	35%	60%	51
Other Effects/Remarks:							
Scores/Effects at 48 hr							
Cornea: Opacity	0	0	2	1	1	1	Mean: 0.8
Area	0	0	4	4	2	4	2.6
Iris: Inflamm.	0	0	1	1	1	1	0.8
Conjunct: Redness	2	1	3	3	3	3	2.2
Chemosis	1	0	4	4	3	3	2.6
Discharge	1	1	3	3	3	3	2.2
Fluorescein Exam.	0%	0%	80%	75%	15%	35%	34
Other Effects/Remarks:							

(Continued)

Table 5 (Continued)

Primary Eye Irritation-Rabbit

Material: Methyl CELLOSOLVE Acetate Sample No.: 46-352 Amount: 0.1 ml

Rabbit No:	84-495	84-497	84-498	84-388	84-397	84-461	
Sex	Male	Male	Male	Female	Female	Female	
Date Dosed	02/28/84	02/28/84	02/28/84	02/28/84	02/28/84	02/28/84	
<b>Scores/Effects at 72 hr</b>							
Cornea: Opacity	0	0	2	1	0	1	Mean 0.7
Area	0	0	4	4	0	1	1.5
Iris: Inflamm.	0	0	1	1	0	0	0.3
Conjunct: Redness	1	1	3	3	2	2	2.0
Chemosis	1	0	3	2	1	1	1.3
Discharge	0	0	1	2	1	1	0.8
Fluorescein Exam.	0%	0%	45%	40%	0%	5%	15%
Other Effects/Remarks: Rabbits 497, 498, 388 and 461 with minor necrosis of the nictitating membrane.							

<b>Scores/Effects at 7 Days</b>							
Cornea: Opacity	0	0	2	0	0	0	Mean 0.3
Area	0	0	4	0	0	0	0.7
Iris: Inflamm.	0	0	1	0	0	0	0.2
Conjunct: Redness	0	1	3	0	0	1	0.8
Chemosis	0	0	2	0	0	0	0.3
Discharge	0	0	3	0	0	0	0.5
Fluorescein Exam.	0%	0%	35%	5%	0%	0%	7%
Other Effects/Remarks:							

<b>Scores/Effects at 14 Days</b>							
Cornea: Opacity	0	0	1	0	0	0	Mean 0.2
Area	0	0	4	0	0	0	0.7
Iris: Inflamm.	0	0	1	0	0	0	0.2
Conjunct: Redness	0	0	3	0	0	0	0.5
Chemosis	0	0	2	0	0	0	0.3
Discharge	0	0	3	0	0	0	0.5
Fluorescein Exam.	0%	0%	35%	0%	0%	0%	6%
Other Effects/Remarks:							

<b>Scores/Effects at 21 Days</b>							
Cornea: Opacity	0	0	2	0	0	0	Mean 0.3
Area	0	0	2	0	0	0	0.3
Iris: Inflamm.	0	0	1	0	0	0	0.2
Conjunct: Redness	0	0	3	0	0	0	0.5
Chemosis	0	0	2	0	0	0	0.3
Discharge	0	0	3	0	0	0	0.5
Fluorescein Exam.	0%	0%	20%	0%	0%	0%	3%
Other Effects/Remarks: Rabbit 498 with corneal vascularization.							

Table 6

## Primary Eye Irritation-Rabbit

Material: Methyl CELLOSOLVE Acetate Sample No.: 46-352 Amount: 0.01 r

Rabbit No:	84-553	84-554	84-555	84-517	84-599	84-601
Sex	Male	Male	Male	Female	Female	Female
Date Dosed	03/06/84	03/06/84	03/06/84	03/06/84	03/06/84	03/06/84

Scores/Effects at 1 hr							Mean
Cornea:	Opacity	1	0	0	0	0	0.2
	Area	1	0	0	0	0	0.2
Iris:	Inflam.	0	0	0	1	0	0.2
Conjunct:	Redness	1	2	1	2	1	1.3
	Chemosis	1	1	2	2	1	1.3
	Discharge	1	2	2	2	1	1.5
Fluorescein Exam.	-	-	-	-	-	-	-
Other Effects/Remarks:							

Scores/Effects at 4 hr							Mean
Cornea:	Opacity	1	0	1	0	0	0.3
	Area	1	0	1	0	0	0.3
Iris:	Inflam.	1	1	1	1	0	0.8
Conjunct:	Redness	2	2	2	2	1	1.8
	Chemosis	1	2	2	2	1	1.7
	Discharge	3	3	3	3	2	2.8
Fluorescein Exam.	-	-	-	-	-	-	-
Other Effects/Remarks:							

Scores/Effects at 24 hr							Mean
Cornea:	Opacity	0	0	0	0	0	0.0
	Area	0	0	0	0	0	0.0
Iris:	Inflam.	0	0	0	0	0	0.0
Conjunct:	Redness	1	2	2	1	0	1.2
	Chemosis	0	1	1	0	0	0.3
	Discharge	0	2	2	1	0	0.8
Fluorescein Exam.	5%	0%	0%	0%	0%	0%	1%
Other Effects/Remarks:							

Scores/Effects at 48 hr							Mean
Cornea:	Opacity	0	0	0	0	0	0.0
	Area	0	0	0	0	0	0.0
Iris:	Inflam.	0	0	0	0	0	0.0
Conjunct:	Redness	0	1	1	0	0	0.3
	Chemosis	0	1	0	0	0	0.2
	Discharge	0	0	0	0	0	0.0
Fluorescein Exam.	0%	0%	0%	0%	0%	0%	0%
Other Effects/Remarks:							

(Continued)

Table 6 (Continued)

## Primary Eye Irritation-Rabbit

Material: Methyl CELLOSOLVE Acetate Sample No.: 46-352 Amount: 0.01 ml

Rabbit No:	84-553	84-554	84-555	84-517	84-599	84-601	
Sex	Male	Male	Male	Female	Female	Female	
Date Dosed	03/06/84	03/06/84	03/06/84	03/06/84	03/06/84	03/06/84	
Scores/Effects at 72 hr							Mean
Cornea: Opacity	0	0	0	0	0	0	0.0
Area	0	0	0	0	0	0	0.0
Iris: Inflamm.	0	0	0	0	0	0	0.0
Conjunct: Redness	0	1	1	0	0	0	0.3
Chemosis	0	0	1	0	0	0	0.2
Discharge	0	0	0	0	0	0	0.0
Fluorescein Exam.	0%	0%	0%	0%	0%	0%	0%
Other Effects/Remarks:							

Scores/Effects at 7 Days							Mean
Cornea: Opacity	0	0	0	0	0	0	0.0
Area	0	0	0	0	0	0	0.0
Iris: Inflamm.	0	0	0	0	0	0	0.0
Conjunct: Redness	0	0	0	0	0	0	0.0
Chemosis	0	0	0	0	0	0	0.0
Discharge	0	0	0	0	0	0	0.0
Fluorescein Exam.	0%	0%	0%	0%	0%	0%	0%
Other Effects/Remarks:							

WPC/fcz/0129Z-1

04-18-84

Table 7

## Primary Eye Irritation-Rabbit

Material: Methyl CELLOSOLVE Acetate Sample No.: 46-352 Amount: 0.005 ml.

Rabbit No:	84-569	84-413	84-570	84-523	84-530	84-541
Sex	Male	Male	Male	Female	Female	Female
Date Dosed	03/13/84	03/13/84	03/13/84	03/13/84	03/13/84	03/13/84

		Scores/Effects at 1 hr						Mean
Cornea:	Opacity	1	1	0	1	1	1	0.8
	Area	1	1	0	1	1	1	0.8
Iris:	Inflam.	0	0	0	1	0	1	0.3
Conjunct:	Redness	2	1	1	1	1	1	1.2
	Chemosis	1	1	1	1	1	1	1.0
	Discharge	2	2	1	2	2	2	1.8
Fluorescein Exam.	-	-	-	-	-	-	-	-
Other Effects/Remarks:								

		Scores/Effects at 4 hr						Mean
Cornea:	Opacity	0	0	0	0	1	0	0.2
	Area	0	0	0	0	1	0	0.2
Iris:	Inflam.	0	0	0	1	0	1	0.3
Conjunct:	Redness	2	2	2	3	2	3	2.3
	Chemosis	1	1	2	2	1	2	1.5
	Discharge	2	3	3	3	3	3	2.8
Fluorescein Exam.	-	-	-	-	-	-	-	-
Other Effects/Remarks:								

		Scores/Effects at 24 hr						Mean
Cornea:	Opacity	0	0	0	0	0	0	0.0
	Area	0	0	0	0	0	0	0.0
Iris:	Inflam.	0	0	0	1	0	0	0.2
Conjunct:	Redness	2	1	1	3	1	2	1.7
	Chemosis	1	1	0	2	1	1	1.0
	Discharge	1	1	1	3	1	1	1.3
Fluorescein Exam.	20%	0%	0%	10%	25%	30%	14%	
Other Effects/Remarks:								

		Scores/Effects at 48 hr						Mean
Cornea:	Opacity	0	0	0	0	0	0	0.0
	Area	0	0	0	0	0	0	0.0
Iris:	Inflam.	0	0	0	0	0	0	0.0
Conjunct:	Redness	0	1	0	1	0	0	0.3
	Chemosis	0	0	0	0	0	0	0.0
	Discharge	0	0	0	0	0	0	0.0
Fluorescein Exam.	0%	0%	0%	0%	0%	10%	2%	
Other Effects/Remarks:								

(Continued)

Table 7 (Continued)Primary Eye Irritation-Rabbit

Material: Methyl CELLOSOLVE Acetate Sample No.: 46-352 Amount: 0.005 ml

Rabbit No:	84-569	84-413	84-570	84-523	84-530	84-541	
Sex	Male	Male	Male	Female	Female	Female	
Date Dosed	03/13/84	03/13/84	03/13/84	03/13/84	03/13/84	03/13/84	
Scores/Effects at 72 hr							Mean
Cornea: Opacity	0	0	0	0	0	0	0.0
Area	0	0	0	0	0	0	0.0
Iris: Inflamm.	0	0	0	0	0	0	0.0
Conjunct: Redness	0	0	0	0	0	0	0.0
Chemosis	0	0	0	0	0	0	0.0
Discharge	0	0	0	0	0	0	0.0
Fluorescein Exam.	0%	0%	0%	0%	0%	0%	0.0
Other Effects/Remarks:							0%

WPC/fcz/01282-2

04-24-84

Table 8

Summary of Eye Scores

Material: Methyl CELLOSOLVE Acetate

Sample No. 46-352

OBSERVATION	OBSERVATION TIMES									
	1 Hr	4 Hr	24 Hr	48 Hr	72 Hr	7 Days	10 Days	14 Days	21 Day	
CORNEA										
Opacity:	Range	0 to 1	All 1	0 to 1	0 to 2	0 to 2	0 to 2	-	0 to 1	0 to 2
	Mean	0.8	1.0	0.7	0.8	0.7	0.3	-	0.2	0.3
Area:	Range	0 to 2	1 to 2	0 to 4	0 to 4	0 to 4	0 to 4	-	0 to 4	0 to 2
	Mean	1.3	1.7	1.7	2.3	1.5	0.7	-	0.7	0.2
IRIS										
Injury:	Range	0 to 1	All 1	0 to 1	0 to 1	0 to 1	0 to 1	-	0 to 1	0 to 1
	Mean	0.8	1.0	0.8	0.7	0.3	0.2	-	0.2	0.2
CONJUNCTIVAE										
Redness:	Range	1 to 2	2 to 3	1 to 3	1 to 3	1 to 3	0 to 3	-	0 to 3	0 to 3
	Mean	1.8	2.2	2.3	2.5	2.0	0.8	-	0.5	0.5
Chemosis:	Range	All 2	3 to 4	1 to 4	0 to 4	0 to 3	0 to 2	-	0 to 2	0 to 2
	Mean	2.0	3.2	2.8	2.5	1.3	0.3	-	0.3	0.3
Discharge:	Range	All 3	All 3	1 to 3	1 to 3	0 to 2	0 to 3	-	0 to 3	0 to 3
	Mean	3.0	3.0	2.7	2.3	0.8	0.5	-	0.5	0.5
Volume Instilled: 0.1 ml										
CORNEA										
Opacity:	Range	0 to 1	0 to 1	All 0	All 0	All 0	All 0	-	-	-
	Mean	0.2	0.3	0.0	0.0	0.0	0.0	-	-	-
Area:	Range	0 to 1	0 to 1	All 0	All 0	All 0	All 0	-	-	-
	Mean	0.2	0.3	0.0	0.0	0.0	0.0	-	-	-
IRIS										
Injury:	Range	0 to 1	0 to 1	All 0	All 0	All 0	All 0	-	-	-
	Mean	0.2	0.8	0.0	0.0	0.0	0.0	-	-	-
CONJUNCTIVAE										
Redness:	Range	1 to 2	1 to 2	0 to 2	0 to 1	0 to 1	All 0	-	-	-
	Mean	1.3	1.8	1.2	0.3	0.3	0.0	-	-	-
Chemosis:	Range	1 to 2	1 to 2	0 to 1	0 to 1	0 to 1	All 0	-	-	-
	Mean	1.3	1.7	0.3	0.2	0.2	0.0	-	-	-
Discharge:	Range	1 to 2	2 to 3	0 to 2	All 0	All 0	All 0	-	-	-
	Mean	1.5	2.8	0.8	0.0	0.0	0.0	-	-	-
Volume Instilled: 0.01 ml										
CORNEA										
Opacity:	Range	0 to 1	0 to 1	All 0	All 0	All 0	-	-	-	-
	Mean	0.8	0.2	0.0	0.0	0.0	-	-	-	-
Area:	Range	0 to 1	0 to 1	All 0	All 0	All 0	-	-	-	-
	Mean	0.8	0.2	0.0	0.0	0.0	-	-	-	-
IRIS										
Injury:	Range	0 to 1	0 to 1	0 to 1	All 0	All 0	-	-	-	-
	Mean	0.3	0.3	0.2	0.0	0.0	-	-	-	-
CONJUNCTIVAE										
Redness:	Range	1 to 2	2 to 3	1 to 3	0 to 1	All 0	-	-	-	-
	Mean	1.2	2.3	1.7	0.3	0.0	-	-	-	-
Chemosis:	Range	All 1	1 to 2	0 to 2	All 0	All 0	-	-	-	-
	Mean	1.0	1.5	1.0	0.0	0.0	-	-	-	-
Discharge:	Range	1 to 2	2 to 3	1 to 3	All 0	All 0	-	-	-	-
	Mean	1.8	2.8	1.3	0.0	0.0	-	-	-	-

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