

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

002532

DATE: July 17, 1979

SUBJECT: Eye Irritation of Xylene and Related Compounds

FROM: K. L. Bailey
Toxicology Branch/HED (TS-769)

K. L. Bailey

Caswell #906

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TO: R. Green
PM Team #12, WSM, RD, IRB

THRU: E. Budd
Section Head, Review Section II
Toxicology Branch/HED (TS-769)

E. Budd

In relation to your question concerning the eye irritation induced by xylene, we are enclosing the B. Jaeger, 6/26/76 memo which specifically considers the eye and dermal irritation of xylene.

Where it is necessary to estimate the eye irritation of aromatic solvents in the absence of adequate toxicologic data, we recommend that the aromatic solvent or mixture of aromatic solvents be treated as if it were composed entirely of xylene. Thus, by way of example, the solvent Tennaco 500-100 which contains 61% C₉ aromatics would be treated as if it were 61% xylene; from the attached B. Jaeger memo, it would be placed in Toxicity Category I - DANGER - on the basis of eye irritation.

It is to be emphasized that this recommendation is a "rough and ready" approximation and should only be used when it is necessary to roughly estimate the eye irritation properties of an aromatic solvent in the absence of adequate toxicologic data.

TOX:HED:OPP:OTS:RD EBUDD:sb 7/17/79 X73710

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

002532

SUBJECT: Eye and Skin Irritation for products containing Xylene

DATE: July 26, 1976

FROM: Bruce Jaeger, Technical Leader
Reregistration Task Force

All RTF members

Recent studies with varying concentrations of xylene have demonstrated the following, with regard to eye and skin irritation:

Dermal Irritation:

30% Xylene	P.I. Index 2.59/8.0
45% Xylene	P.I. Index 3.26/8.0
60% Xylene	P.I. Index 3.25/8.0

Eye Irritation

30% Xylene	Corneal opacity in 2/6 Rabbits on day 7. Clear by day 14 (24 hr 47.5/110; 48hr 49.17/110 and 72 hr 47.17/110; 7 day 2.5/110)
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45% Xylene	Corneal opacity in 5/6 at day 7 and 1/6 at day 14. (24 hrs 32.33/110; 48 hr 36.9/110; 72 hr 37.01/110; 7 day 29.16/110)
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60% Xylene	Corneal opacity in 6/6 at day 7 and 4/6 at day 14 (24 hr 48.17/110; 48 hr 47.83/110; 72 hr 50.67/110; 7 day 36.33/110)
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The above data indicates that xylene itself, would require the signal word DANGER for concentrations 30% and greater, based on eye irritation results. It causes mild skin irritation at 30%, and moderate skin irritation at 45% and greater. Based on these data, products formulated with xylene in concentrations of 30% and greater will require the signal word DANGER, and appropriate precautionary statements associated with eye irritation. This information should be utilized when writing Label Guidance Packages for products formulated with xylene.

cc: John Carley

2

00252

Table 1. Dermal Irritation scores of rabbits following treatment with 30% Xylenes

INDIVIDUAL SCORES

Rabbit No.	Erythema - Eschar														Edema															
	ABRADED							UNABRADED							ABRADED							UNABRADED								
	Day 1		Day 2		Day 3		Day 7		Day 14		Day 1		Day 2		Day 3		Day 7		Day 14		Day 1		Day 2		Day 3		Day 7		Day 14	
1	2	2	2	2	2	2	2	1	1	3	3	3	3	3	1	1	1	1	0	0	1	1	1	1	0	0	0	0	0	0
2	2	1	1	2	2	1	2	2	1	2	1	1	2	2	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	
3	2	2	2	2	2	1	2	2	2	2	2	2	3	3	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	
4	3	1	1	1	2	0	3	1	1	1	1	1	2	2	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	
5	2	1	1	1	2	1	2	2	2	2	2	2	3	3	2	2	0	0	0	0	1	0	0	0	0	0	0	0	0	
6	2	1	1	1	2	0	2	2	2	2	2	2	3	3	0	2	0	0	0	0	2	0	0	0	0	0	0	0	0	
TOTAL	13	8	8	12	4	4	14	14	11	11	11	16	16	5	7	1	1	0	0	1.17	1	1	1	1	0	0	0	0	0	
AVERAGE	2.17	1.33	1.33	2.0	0.67	0.67	2.33	2.33	1.83	1.83	1.83	2.67	2.67	0.83	1.17	0.17	0.17	0	0	1.17	0.17	0.17	0.17	0	0	0	0	0	0	0

Average scores and Primary Irritation Index

	Erythema & Eschar		Edema	
	Abraded 24 hrs	Unabraded 24 hrs	Abraded 24 hrs	Unabraded 24 hrs
Subtotal	2.17	1.83	1.17	0.17
Abraded 24 hrs	2.17		1.17	
Unabraded 24 hrs	1.33		0.17	
Subtotal	2.33		1.17	
Abraded 24 hrs	1.83		0.17	
Subtotal	7.66		2.68	

TOTAL $\frac{10.3}{4} =$ Primary Irritation Index 2.59

906

3

002532

NP 479 - Xylene 45%

Table 2. Dermal Irritation scores of rabbits following treatment with 45% Xylenes

INDIVIDUAL SCORES

Rabbit No.	Erythema - Eschar				Edema					
	ABRADED		UNABRADED		ABRADED		UNABRADED			
	D a y		D a y		D a y		D a y			
1	1	2	3	7	14	1	2	3	7	14
2	3	2	2	3	0	2	1	1	0	0
3	3	2	2	3	0	2	1	1	1	0
4	3	2	2	3	0	2	1	1	1	0
5	3	2	2	3	0	2	1	1	1	0
6	2	1	1	2	0	1	0	0	0	0
TOTAL	17	11	11	17	1	11	5	5	5	0
AVERAGE	2.83	1.83	1.83	2.83	0.17	1.83	0.83	0.83	0.83	0

Average scores and Primary Irritation Index

Erythema & Eschar	Abraded 24 hrs	2.83
	72 hrs	1.83
	Unabraded 24 hrs	2.83
	72 hrs	1.83
	Subtotal	8.52
Edema	Abraded 24 hrs	1.83
	72 hrs	0.83
	Unabraded 24 hrs	1.83
	72 hrs	0.83
	Subtotal	4.52
TOTAL	$\frac{13.04}{4}$	= Primary Irritation Index 3.26

002532

MP 479 - Xylene 60%

Table 3. Dermal Irritation scores of rabbits following treatment with 60% Xylenes

INDIVIDUAL SCORES

Rabbit No.	Erythema - Eschar				Edema									
	ABRADED		UNABRADED		ABRADED		UNABRADED							
	1	2	3	7	14	1	2	3	7	14				
1	2	1	1	2	1	1	1	2	2	0	0	0	0	
2	3	2	2	2	0	3	2	2	3	1	1	0	0	
3	2	1	1	2	1	1	1	2	2	1	0	0	0	
4	3	1	1	3	1	3	2	1	2	0	0	0	0	
5	3	2	2	3	0	3	1	1	2	0	0	0	0	
6	3	1	1	2	0	3	2	2	3	1	0	0	0	
TOTAL	16	8	8	14	3	16	9	8	14	2	13	4	1	
AVERAGE	2.67	1.33	1.33	2.33	0.5	2.67	1.50	1.33	2.33	0.33	2.17	0.67	0.17	0

Average scores and Primary Irritation Index

Erythema & Eschar

Abraded 24 hrs 2.67

72 hrs 1.33

Unabraded 24 hrs 2.67

72 hrs 1.33

Subtotal

8.00

Edema

Abraded 24 hrs 2.17

72 hrs 0.17

Unabraded 24 hrs 2.33

72 hrs 0.33

Subtotal

5.00

TOTAL

13.00

4

Primary Irritation Index 3.25

5

002532

MP 479 - 30% Xylene

Table 4. Ocular irritation scores of rabbits following treatment with 30% Xylenes.

INDIVIDUAL SCORES

Interval	24 hrs					48 hrs					72 hrs					96 hrs					7th day					14th day											
	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	
Rabbit No.	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	
Cornea																																					
a) Opacity	2	2	2	2	1	1	2	2	2	2	2	2	2	1	2	2	2	2	2	2	2	1	1	1													
b) Area	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4													
Iris																																					
a) Injury	1	1	1	0	0	0	1	1	1	1	0	0	1	1	1	1	0	0	0	0	0	0	0	0													
Conjunctiva																																					
a) Redness	3	3	3	2	3	3	3	3	2	1	3	1	3	3	2	1	3	1																			
b) Chemosis	3	2	1	1	2	1	3	2	0	0	2	0	2	0	2	0	0	1	0																		
c) Discharge	2	3	2	2	2	2	2	2	2	1	1	2	2	2	1	0	0	1																			

Weighted Average Total Scores

	24 hrs	48 hrs	72 hrs	96 hrs	7th day	14th day
Cornea (axbx5) Maximum = 80	33.33	36.67	36.67		2.50	0
Iris (ax5) Maximum = 10	2.50	2.50	2.50		0	0
Conjunctiva (a+b+c)x2 Maximum = 20	11.67	10.00	8.00		0	0

002532

NP 479 - 45% Xylana

Table 5. Ocular irritation scores of rabbits following treatment with 45% Xylenes.

INDIVIDUAL SCORES

Interval	24 hrs					48 hrs					72 hrs					96 hrs					7th day					14th day				
Rabbit No.	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6						
Cornea																														
a) Opacity	1	1	1	1	1	2	1	1	1	2	1	2	1	1	1	1	2	1	2	0	1	1	1	0						
b) Area	4	2	4	4	4	4	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4						
Iris																														
a) Injury	1	0	0	1	0	1	0	0	1	0	1	0	1	0	0	1	0	0	1	0	0	1	0	1						
Conjunctiva																														
a) Redness	3	3	2	3	3	2	3	2	2	2	3	1	3	2	2	3	1							1						
b) Chemosis	3	2	1	2	2	1	2	2	0	1	2	0	1	1	0	1	1	0						0						
c) Discharge	3	2	3	2	3	2	3	2	2	1	2	1	3	1	1	1	2	1						0						

Weighted Average Total Scores

	24 hrs	48 hrs	72 hrs	96 hrs	7th day	14th day
Cornea (axbx5) Maximum = 80	18.33	25.00	26.67	--	25.00	5.00
Iris (ax5) Maximum = 10	1.67	1.67	1.67	--	0.83	0.83
Conjunctiva (a+b+c)x2 Maximum = 20	12.33	10.33	8.67	--	3.33	1.33

002532

MP 479 - Xylene 60%

Table 6. Ocular irritation scores of rabbits following treatment with 60% Xylenes.

INDIVIDUAL SCORES

Interval	24 hrs			48 hrs			72 hrs			96 hrs			7th day			14th day		
Rabbit No.	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6
Cornea																		
a) Opacity	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
b) Area	3	4	1	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Iris																		
a) Injury	0	1	0	1	0	0	1	0	0	0	0	0	1	1	0			
Conjunctiva																		
a) Redness	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
b) Chemosis	2	2	3	3	1	2	1	0	1	1	0	0	0	1	0	0	0	0
c) Discharge	2	3	3	2	3	3	1	2	2	2	1	2	1	1	2	1		

Weighted Average Total Scores

	24 hrs	48 hrs	72 hrs	96 hrs	7th day	14th day
Cornea (a+b)x5) Maximum = 80	30.00	36.67	40.00		35.00	14.17
Iris (ax5) Maximum = 10	2.50	0.83	1.67		0.00	0.00
Conjunctiva (a+b+c)x2 Maximum = 20	15.67	10.33	9.00		1.33	0.33